



FEDERAL REGISTER

Vol. 87

Tuesday

No. 224

November 22, 2022

Pages 71203–71502

OFFICE OF THE FEDERAL REGISTER



The **FEDERAL REGISTER** (ISSN 0097-6326) is published daily, Monday through Friday, except official holidays, by the Office of the Federal Register, National Archives and Records Administration, under the Federal Register Act (44 U.S.C. Ch. 15) and the regulations of the Administrative Committee of the Federal Register (1 CFR Ch. I). The Superintendent of Documents, U.S. Government Publishing Office, is the exclusive distributor of the official edition. Periodicals postage is paid at Washington, DC.

The **FEDERAL REGISTER** provides a uniform system for making available to the public regulations and legal notices issued by Federal agencies. These include Presidential proclamations and Executive Orders, Federal agency documents having general applicability and legal effect, documents required to be published by act of Congress, and other Federal agency documents of public interest.

Documents are on file for public inspection in the Office of the Federal Register the day before they are published, unless the issuing agency requests earlier filing. For a list of documents currently on file for public inspection, see www.federalregister.gov.

The seal of the National Archives and Records Administration authenticates the **Federal Register** as the official serial publication established under the Federal Register Act. Under 44 U.S.C. 1507, the contents of the **Federal Register** shall be judicially noticed.

The **Federal Register** is published in paper and on 24x microfiche. It is also available online at no charge at www.govinfo.gov, a service of the U.S. Government Publishing Office.

The online edition of the **Federal Register** is issued under the authority of the Administrative Committee of the Federal Register as the official legal equivalent of the paper and microfiche editions (44 U.S.C. 4101 and 1 CFR 5.10). It is updated by 6:00 a.m. each day the **Federal Register** is published and includes both text and graphics from Volume 1, 1 (March 14, 1936) forward. For more information, contact the GPO Customer Contact Center, U.S. Government Publishing Office. Phone 202-512-1800 or 866-512-1800 (toll free). E-mail, gpocusthelp.com.

The annual subscription price for the **Federal Register** paper edition is \$860 plus postage, or \$929, for a combined **Federal Register**, **Federal Register** Index and List of CFR Sections Affected (LSA) subscription; the microfiche edition of the **Federal Register** including the **Federal Register** Index and LSA is \$330, plus postage. Six month subscriptions are available for one-half the annual rate. The prevailing postal rates will be applied to orders according to the delivery method requested. The price of a single copy of the daily **Federal Register**, including postage, is based on the number of pages: \$11 for an issue containing less than 200 pages; \$22 for an issue containing 200 to 400 pages; and \$33 for an issue containing more than 400 pages. Single issues of the microfiche edition may be purchased for \$3 per copy, including postage. Remit check or money order, made payable to the Superintendent of Documents, or charge to your GPO Deposit Account, VISA, MasterCard, American Express, or Discover. Mail to: U.S. Government Publishing Office—New Orders, P.O. Box 979050, St. Louis, MO 63197-9000; or call toll free 1-866-512-1800, DC area 202-512-1800; or go to the U.S. Government Online Bookstore site, see bookstore.gpo.gov.

There are no restrictions on the republication of material appearing in the **Federal Register**.

How To Cite This Publication: Use the volume number and the page number. Example: 87 FR 12345.

Postmaster: Send address changes to the Superintendent of Documents, Federal Register, U.S. Government Publishing Office, Washington, DC 20402, along with the entire mailing label from the last issue received.

SUBSCRIPTIONS AND COPIES

PUBLIC

Subscriptions:

Paper or fiche	202-512-1800
Assistance with public subscriptions	202-512-1806

General online information 202-512-1530; 1-888-293-6498

Single copies/back copies:

Paper or fiche	202-512-1800
Assistance with public single copies	1-866-512-1800 (Toll-Free)

FEDERAL AGENCIES

Subscriptions:

Assistance with Federal agency subscriptions:

Email	FRSubscriptions@nara.gov
Phone	202-741-6000

The Federal Register Printing Savings Act of 2017 (Pub. L. 115-120) placed restrictions on distribution of official printed copies of the daily **Federal Register** to members of Congress and Federal offices. Under this Act, the Director of the Government Publishing Office may not provide printed copies of the daily **Federal Register** unless a Member or other Federal office requests a specific issue or a subscription to the print edition. For more information on how to subscribe use the following website link: <https://www.gpo.gov/frsubs>.



Contents

Federal Register

Vol. 87, No. 224

Tuesday, November 22, 2022

Agency for International Development

NOTICES

Meetings:
Advisory Committee, 71290

Agriculture Department

See Food and Nutrition Service
See Food Safety and Inspection Service

NOTICES

Agency Information Collection Activities; Proposals, Submissions, and Approvals, 71290–71291

Antitrust Division

NOTICES

Changes under the National Cooperative Research and Production Act:
Homeland Security Technology Consortium, 71357

Bonneville Power Administration

NOTICES

Hearing:
Proposed Modifications to Open Access Transmission Tariff, 71317–71320

Bureau of Consumer Financial Protection

NOTICES

Agency Information Collection Activities; Proposals, Submissions, and Approvals, 71310–71311

Census Bureau

RULES

Resumption of the Population Estimates Challenge Program, 71240–71242

PROPOSED RULES

Resumption of the Population Estimates Challenge Program and Proposed Changes to the Program, 71269–71271

Centers for Disease Control and Prevention

NOTICES

Agency Information Collection Activities; Proposals, Submissions, and Approvals, 71329–71330

Meetings:

Recommendations for Hepatitis C Testing Among Perinatally Exposed Infants and Children—United States, 2023; Webinar, 71330–71332

Children and Families Administration

NOTICES

Agency Information Collection Activities; Proposals, Submissions, and Approvals:
Annual Report on Households Assisted by the Low Income Home Energy Assistance Program, 71332–71333

Civil Rights Commission

NOTICES

Meetings:
Arkansas Advisory Committee, 71298
Connecticut Advisory Committee, 71297
Guam Advisory Committee, 71296–71297
Minnesota Advisory Committee, 71296
Puerto Rico Advisory Committee, 71297–71298

Coast Guard

RULES

Safety Zone:
Ohio River Mile Marker 0.3–1.5, Pittsburgh, PA, 71252–71254
Special Local Regulations:
San Diego Parade of Lights, San Diego, CA, 71251–71252

Commerce Department

See Census Bureau

See Foreign-Trade Zones Board

See Industry and Security Bureau

See International Trade Administration

See National Oceanic and Atmospheric Administration

See Patent and Trademark Office

Community Development Financial Institutions Fund

NOTICES

Funding Opportunity:
Calendar Year 2022 Allocation Round of the New Markets Tax Credit Program, 71409–71419

Consumer Product Safety Commission

RULES

Children's Gasoline Burn Prevention Act Regulation, 71242–71247

Copyright Office, Library of Congress

PROPOSED RULES

Termination Rights and the Music Modernization Act's Blanket License, 71286

Defense Department

NOTICES

Meetings:

Defense Business Board; Change to Agenda, 71312–71313
TRICARE; Calendar Year 2023:
TRICARE Prime and TRICARE Select Out-of-Pocket Expenses, 71313–71314

Drug Enforcement Administration

RULES

Schedules of Controlled Substances:
Placement of Mesocarb in Schedule I, 71247–71250

Education Department

NOTICES

Agency Information Collection Activities; Proposals, Submissions, and Approvals:
Application for Grants under the Native American-Serving Nontribal Institutions Program, 71314
Bipartisan Safer Communities Act, Stronger Connections Grant Program, 71314–71315
Evaluating the Impact of the Professional Learning Community: Emergent Literacy, 71315–71316

Election Assistance Commission

NOTICES

Meetings; Sunshine Act, 71316–71317

Employee Benefits Security Administration**NOTICES**

Exemption:

Certain Prohibited Transaction Restrictions Involving the Children's Hospital of Philadelphia Pension Plan for Union-Represented Employees, Philadelphia, PA, 71358–71361

Energy Department

See Bonneville Power Administration

See Federal Energy Regulatory Commission

NOTICES

Meetings:

High Energy Physics Advisory Panel, 71320
National Petroleum Council, 71320–71321

Environmental Protection Agency**RULES**

Air Quality State Implementation Plans; Approvals and Promulgations:
Colorado; Reg 3 NSR and APEN Updates, 71258–71262

PROPOSED RULES

Air Quality State Implementation Plans; Approvals and Promulgations:
North Carolina; Minor Revisions to Nitrogen Oxides Rule, 71286–71289

NOTICES

Cancellation Order for Certain Pesticide Registrations and Amendments to Terminate Uses, 71325–71327

Requests for Nominations:

Science Advisory Board Inorganic Arsenic Review Panel, 71328–71329

Requests to Voluntarily Cancel Certain Pesticide

Registrations and Amend Registrations to Terminate Certain Uses, 71321–71325

Federal Aviation Administration**RULES**

Airspace Designations and Reporting Points:
Evansville, IN, 71238–71239

Increase the Duration of Aircraft Registration, 71210–71218

Medical Certification Standards for Commercial Balloon Operations, 71218–71238

Yaw Maneuver Conditions:

Rudder Reversals, 71203–71210

PROPOSED RULES

Airspace Designations and Reporting Points:

Vicinity of Wolbach, NE, 71266–71269

Airworthiness Directives:

Schempp-Hirth Flugzeugbau GmbH Gliders, 71264–71266

NOTICES

Agency Information Collection Activities; Proposals, Submissions, and Approvals:

Certification of Aircraft and Airmen for the Operation of Light-Sport Aircraft, 71392

Meetings:

Aviation Rulemaking Advisory Committee, 71391–71392

Federal Election Commission**NOTICES**

Meetings; Sunshine Act, 71329

Federal Energy Regulatory Commission**NOTICES**

Combined Filings, 71321

Federal Highway Administration**NOTICES**

Environmental Impact Statements; Availability, etc.:

Contra Costa, Alameda, and San Joaquin Counties, CA, 71397–71398

Maui, HI, 71392–71397

Federal Railroad Administration**NOTICES**

Petition for Extension of Waiver of Compliance, 71398–71399

Federal Transit Administration**NOTICES**

Fiscal Year 2023 Competitive Funding Opportunity:

Transit Standards Development, 71399–71404

Fish and Wildlife Service**PROPOSED RULES**

Endangered and Threatened Species:

Designation of Critical Habitat for Florida Bonneted Bat, 71466–71501

NOTICES

John H. Chafee Coastal Barrier Resources System:

Michigan, Minnesota, Mississippi, North Carolina, Ohio, South Carolina, Texas, and Wisconsin; Draft 5-Year Review Boundaries, 71352–71356

Food and Drug Administration**NOTICES**

Agency Information Collection Activities; Proposals, Submissions, and Approvals:

Study of Assessing Physiological, Neural and Self-Reported Response to Tobacco Education Messages, 71335–71338

Meetings:

Science Board to the Food and Drug Administration Advisory Committee, 71334–71335

Statement of Organization, Functions, and Delegations of Authority; Correction, 71333–71334

Food and Nutrition Service**NOTICES**

Agency Information Collection Activities; Proposals, Submissions, and Approvals:

Supplemental Nutrition Assistance Program Emergency Allotments (COVID–19), 71294–71296

Food Safety and Inspection Service**NOTICES**

Use of a Non-Destructive Surface Sampling Device to

Sample Domestic Beef Manufacturing Trimmings and Bench Trim, 71291–71294

Foreign-Trade Zones Board**NOTICES**

Proposed Production Activity:

Tesla, Inc., Foreign-Trade Zone 126, Reno, NV, 71298

Gulf Coast Ecosystem Restoration Council**NOTICES**

Senior Executive Service Performance Review Board, 71329

Health and Human Services Department

See Centers for Disease Control and Prevention

See Children and Families Administration

See Food and Drug Administration

See Health Resources and Services Administration

See National Institutes of Health
See Substance Abuse and Mental Health Services Administration

NOTICES

Agency Information Collection Activities; Proposals, Submissions, and Approvals, 71341–71342

Meetings:

National Committee on Vital and Health Statistics, 71340–71341

Health Resources and Services Administration**NOTICES**

Agency Information Collection Activities; Proposals, Submissions, and Approvals:

Ryan White HIV/AIDS Program: Allocations Forms, 71339–71340

Requests for Nominations:

Advisory Committee on Infant and Maternal Mortality, 71338–71339

Homeland Security Department

See Coast Guard

NOTICES

Meetings:

Homeland Security Advisory Council, 71348

Housing and Urban Development Department**NOTICES**

Agency Information Collection Activities; Proposals, Submissions, and Approvals:

Certified Housing Counselor Registration, 71349–71350

Disaster Recovery Grant Reporting System, 71351–71352

Land Survey Report for Insured Multifamily Projects, 71350–71351

Management Certification and Entity Profile, 71348–71349

Industry and Security Bureau**NOTICES**

Agency Information Collection Activities; Proposals, Submissions, and Approvals:

Foreign Availability Procedures, 71299–71300

Report of Requests for Restrictive Trade Practice or Boycott, 71298–71299

Interior Department

See Fish and Wildlife Service

See Land Management Bureau

See National Park Service

Internal Revenue Service**PROPOSED RULES**

Guidance:

Foreign Tax Credit, 71271–71286

International Trade Administration**NOTICES**

Antidumping or Countervailing Duty Investigations, Orders, or Reviews:

Carbon and Alloy Steel Threaded Rod from the People's Republic of China; Correction, 71302

Wooden Bedroom Furniture from the People's Republic of China, 71300–71302

Application(s) for Duty-Free Entry of Scientific Instruments:

University of South Florida, et. al, 71302–71303

Justice Department

See Antitrust Division

See Drug Enforcement Administration

Labor Department

See Employee Benefits Security Administration

See Occupational Safety and Health Administration

Land Management Bureau**NOTICES**

Plats of Survey:

Colorado, 71356

Library of Congress

See Copyright Office, Library of Congress

Maritime Administration**NOTICES**

Meetings:

U.S. Merchant Marine Academy Board of Visitors, 71404–71405

National Aeronautics and Space Administration**RULES**

Social Security Number Fraud Prevention Act Implementation, 71240

National Archives and Records Administration**NOTICES**

Meetings:

Advisory Committee on the Records of Congress, 71362–71363

National Credit Union Administration**NOTICES**

Agency Information Collection Activities; Proposals, Submissions, and Approvals, 71363

National Institutes of Health**NOTICES**

Charter Amendments, Establishments, Renewals and Terminations:

National Cancer Institute Council of Research Advocates, 71343

Meetings:

Advisory Committee to the Director, 71342

Center for Scientific Review, 71343–71345

National Cancer Institute, 71344–71345

National Institute of Allergy and Infectious Diseases, 71342, 71344–71345

National Institute of Environmental Health Sciences, 71343–71344

National Institute on Alcohol Abuse and Alcoholism, 71345–71346

National Library of Medicine; Cancellation, 71343

National Oceanic and Atmospheric Administration**RULES**

Fisheries off West Coast States:

West Coast Salmon Fisheries; Amendment 23 to the Pacific Coast Salmon Fishery Management Plan, 71262–71263

NOTICES

Meetings:

Pacific Fishery Management Council, 71303

Permits; Applications, Issuances, etc.:

Marine Mammals; File No. 24334, 71303–71304

National Park Service**NOTICES**

Meetings:

Advisory Committee on Reconciliation in Place Names,
71357

National Science Foundation**NOTICES**

Meetings; Sunshine Act, 71363

National Transportation Safety Board**NOTICES**

Meetings; Sunshine Act, 71363–71364

Nuclear Regulatory Commission**RULES**

Guidance:

Fitness for Duty Drug Testing Requirements, 71422–
71463

NOTICES

Export License Application:

Perma-Fix Northwest Richland, Inc., 71364–71365

Requests for Nominations:

Advisory Committee on the Medical Uses of Isotopes,
71365–71366

Occupational Safety and Health Administration**NOTICES**

Nationally Recognized Testing Laboratories:

TUV Rheinland of North America, Inc.; Application for
Expansion of Recognition, 71361–71362

Patent and Trademark Office**NOTICES**

Agency Information Collection Activities; Proposals,

Submissions, and Approvals:

Deposit of Biological Materials, 71304–71306

Legal Processes, 71306–71307

Post Allowance and Reissue, 71307–71310

Pipeline and Hazardous Materials Safety Administration**NOTICES**

Hazardous Materials:

Actions on Special Permits, 71406–71407

Applications for New Special Permits, 71406

Applications for Special Permits, 71405

Postal Regulatory Commission**NOTICES**

New Postal Products, 71366–71367

Postal Service**NOTICES**

Addition of USPS Connect Local Mail, 71367

Science and Technology Policy Office**NOTICES**

Request for Information:

Clinical Research Infrastructure and Emergency Clinical
Trials, 71368

Sustainability of Microgravity R and D during and
beyond ISS Transition; Correction, 71367

Securities and Exchange Commission**NOTICES**

Agency Information Collection Activities; Proposals,
Submissions, and Approvals, 71384–71385

Filings:

24X National Exchange LLC, 71388

Self-Regulatory Organizations; Proposed Rule Changes:

Cboe BZX Exchange, Inc., 71389

Investors Exchange, LLC, 71381–71384

MIAX PEARL, LLC, 71368–71372, 71375–71378

Nasdaq BX, Inc., 71385–71388

Nasdaq PHLX, LLC, 71372–71375

National Securities Clearing Corp., 71379–71381

NYSE Arca, Inc., 71389–71391

Small Business Administration**NOTICES**

Disaster Declaration:

Texas, 71391

State Department**RULES**

International Traffic in Arms:

Prohibited Exports, Imports, and Sales to or from Certain
Countries, Cyprus, 71250–71251

Substance Abuse and Mental Health Services Administration**NOTICES**

Agency Information Collection Activities; Proposals,

Submissions, and Approvals, 71346–71348

Transportation Department

See Federal Aviation Administration

See Federal Highway Administration

See Federal Railroad Administration

See Federal Transit Administration

See Maritime Administration

See Pipeline and Hazardous Materials Safety
Administration

NOTICES

Agency Information Collection Activities; Proposals,

Submissions, and Approvals:

Technical Assistance PRA, 71408

Treasury Department

See Community Development Financial Institutions Fund

See Internal Revenue Service

Veterans Affairs Department**RULES**

Acquisition Regulation:

Acquisition Planning; Required Sources of Supplies and
Services; Market Research; and Small Business
Programs; Correction, 71262

Readjustment Counseling Service Scholarship Program,
71254–71258

Separate Parts In This Issue**Part II**

Nuclear Regulatory Commission, 71422–71463

Part III

Interior Department, Fish and Wildlife Service, 71466–
71501

Reader Aids

Consult the Reader Aids section at the end of this issue for
phone numbers, online resources, finding aids, and notice
of recently enacted public laws.

To subscribe to the Federal Register Table of Contents electronic mailing list, go to <https://public.govdelivery.com/accounts/USGPOOFR/subscriber/new>, enter your e-mail address, then follow the instructions to join, leave, or manage your subscription.

CFR PARTS AFFECTED IN THIS ISSUE

A cumulative list of the parts affected this month can be found in the Reader Aids section at the end of this issue.

10 CFR

2671422

14 CFR

2571203

4771210

6171218

6871218

7171238

121271240

Proposed Rules:

3971264

7171266

15 CFR

9071240

Proposed Rules:

9071269

16 CFR

146071242

21 CFR

130871247

22 CFR

12671250

26 CFR**Proposed Rules:**

171271

33 CFR

10071251

16571252

37 CFR**Proposed Rules:**

21071286

38 CFR

1771254

40 CFR

5271258

Proposed Rules:

5271286

48 CFR

81971262

85271262

50 CFR

66071262

Proposed Rules:

1771466

Rules and Regulations

Federal Register

Vol. 87, No. 224

Tuesday, November 22, 2022

This section of the FEDERAL REGISTER contains regulatory documents having general applicability and legal effect, most of which are keyed to and codified in the Code of Federal Regulations, which is published under 50 titles pursuant to 44 U.S.C. 1510.

The Code of Federal Regulations is sold by the Superintendent of Documents.

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 25

[Docket No.: FAA-2018-0653; Amdt. No. 25-147]

RIN 2120-AK89

Yaw Maneuver Conditions—Rudder Reversals

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule.

SUMMARY: The FAA is adding a new load condition to the design standards for transport category airplanes. The new load condition requires such airplanes to be designed to withstand the loads caused by rapid reversals of the rudder pedals, and applies to transport category airplanes that have a powered rudder control surface or surfaces. This rule is necessary because accident and incident data show that pilots sometimes make rudder reversals during flight, even though such reversals are unnecessary and discouraged by flightcrew training programs. The current design standards do not require the airplane structure to withstand the loads that may result from such reversals. If the loads on the airplane exceed those for which it is designed, the airplane structure may fail, resulting in catastrophic loss of control of the airplane. This final rule aims to prevent structural failure of the rudder and vertical stabilizer that may result from these rudder reversals.

DATES: Effective January 23, 2023.

ADDRESSES: For information on where to obtain copies of rulemaking documents and other information related to this final rule, see “How To Obtain Additional Information” in the **SUPPLEMENTARY INFORMATION** section of this document.

FOR FURTHER INFORMATION CONTACT: For technical questions concerning this

action, contact Todd Martin, Materials and Structural Properties Section, AIR-621, Policy and Innovation Division, Aircraft Certification Service, Federal Aviation Administration, 2200 South 216th Street, Des Moines, WA 98198; telephone and fax (206) 231-3210; email Todd.Martin@faa.gov.

SUPPLEMENTARY INFORMATION:

Authority for This Rulemaking

The FAA’s authority to issue rules on aviation safety is found in Title 49 of the United States Code. Subtitle I, Section 106 describes the authority of the FAA Administrator. Subtitle VII, Aviation Programs, describes in more detail the scope of the agency’s authority.

This rulemaking is promulgated under the authority described in Subtitle VII, Part A, Subpart III, Section 44701, “General Requirements.” Under that section, the FAA is charged with promoting safe flight of civil aircraft in air commerce by prescribing regulations and minimum standards for the design and performance of aircraft that the Administrator finds necessary for safety in air commerce. This regulation is within the scope of that authority. It prescribes new safety standards for the design of transport-category airplanes.

I. Overview of Final Rule

This rule adds a new load condition to the design standards in title 14, Code of Federal Regulations (14 CFR) part 25, to require transport category airplanes that have a powered rudder control surface or surfaces to be designed to withstand the loads caused by rapid reversals of the rudder pedals. Specifically, applicants for design approval must show that their proposed airplane design can withstand an initial full rudder pedal input, followed by three full-pedal reversals at the maximum sideslip angle, followed by return of the rudder to neutral. Due to the rarity of such multiple reversals, the rule specifies the new load condition is an ultimate load condition rather than a limit load condition. Consequently, the applicant does not have to apply an additional factor of safety to the calculated load levels.¹

¹ The terms “limit,” “ultimate,” and “factor of safety” are addressed in §§ 25.301, 25.303, and 25.305. To summarize, design loads are typically expressed in terms of limit loads, which are then multiplied by a factor of safety, usually 1.5, to determine ultimate loads. In this final rule, the

This final rule affects manufacturers of transport category airplanes applying for a new type certificate after the effective date of the final rule. The rule may also affect applicants applying for an amended or supplemental type certificate as determined under 14 CFR 21.101, “Designation of applicable regulations,” after the effective date of the final rule.

The final rule will entail minimal cost, with expected net safety benefits from the reduced risk of rudder reversal accidents.

II. Background

A. Statement of the Problem

The rudder is a vertical control surface on the tail of most airplanes that helps the airplane to turn. Rudder control systems are either powered or unpowered.² Accident and incident data show pilots sometimes make multiple and unnecessary rudder reversals during flight. In addition, FAA-sponsored research³ indicates that pilots use the rudder more often than previously expected and often in ways not recommended by manufacturers. Section 25.1583(a)(3)(ii) requires manufacturers to provide documentation that warns pilots against making large and rapid control reversals, as they may result in

design loads are expressed as ultimate loads and no additional safety factor is applied.

² A powered rudder control surface is one in which the force required to deflect the surface against the airstream is generated or augmented by non-mechanical means, such as hydraulic or electric systems. Powered rudder control systems include fly-by-wire and hydro-mechanical systems. An unpowered rudder control surface is one for which the force required to deflect the rudder control surface is transmitted from the pilot’s rudder pedal directly to the rudder control surface through mechanical means. Unpowered rudder control systems are also known as mechanical systems. Incorporation of a powered yaw damper into an otherwise unpowered rudder control system does not constitute a powered rudder control system. Other powered systems, such as electrical, hydraulic, or pneumatic systems, may aid in the reduction of pedal forces required for single engine-out operations or to trim out pedal force to maintain a steady heading. However, if such a powered system does not contribute to hinge moment generation (the twisting force on the rudder surface) during maneuvering of a fully operational airplane, it is not a powered rudder control system.

³ Report No. DOT/FAA/AM-10/14, “An International Survey of Transport Airplane Pilots’ Experiences and Perspectives of Lateral/Directional Control Events and Rudder Issues in Transport Airplanes (Rudder Survey),” dated October 2010, is available in the Docket and at http://www.faa.gov/data_research/research/med_humanfacs/oamtechreports/2010s/media/201014.pdf.

structural failures at any speed, including airspeeds below the design maneuvering speed (V_A). Despite the § 25.1583(a)(3)(ii) requirement, and that such rudder reversals are unnecessary and discouraged by flightcrew training programs, these events continue to occur.

Section 25.351 (“Yaw maneuver conditions”), which sets forth the standard for protecting the airplane’s vertical stabilizer from pilot-commanded maneuver loads, only addresses a single, full rudder input at airspeeds up to the design diving speed (V_D).⁴ This design standard does not protect the airplane from the loads imposed by repeated inputs in opposing directions, or rudder reversals.⁵ If the loads on the vertical stabilizer exceed those for which it is designed, the vertical stabilizer may fail, resulting in the catastrophic loss of airplane control.

The primary example of this risk is the crash of American Airlines Flight 587 (AA587), which occurred near Queens, New York, on November 12, 2001, and resulted in the death of all 260 passengers and crew aboard and of five persons on the ground. The National Transportation Safety Board (NTSB) found that the probable cause of the accident was “the in-flight separation of the vertical stabilizer [airplane fin] as a result of loads above ultimate design created by the first officer’s unnecessary and excessive rudder pedal inputs.”⁶ The NTSB also noted that contributing to these rudder pedal inputs were characteristics of the Airbus A300–600 rudder system design and elements of the American Airlines Advanced Aircraft Maneuvering Program.

Although the AA587 accident is the only catastrophic accident resulting from rudder reversals, other notable accidents and incidents involving airplanes that have a powered control ruder surface have occurred.⁷ Ultimate

loads were exceeded in two of the other notable rudder reversal events: an incident involving Interflug (Moscow, February 11, 1991) and an accident involving American Airlines Flight 903 (AA903) (near West Palm Beach, Florida, May 12, 1997).⁸ The Interflug incident involved multiple rudder reversals, and loads of 1.55 and 1.35 times the limit load were recorded. For the AA903 incident, eight rudder reversals occurred, and a load of 1.53 times the limit load was recorded.⁹ A catastrophe similar to AA587 was averted in these two events only because the vertical stabilizers were stronger than required by design standards.¹⁰ In another event, an incident involving Air Canada Flight 190 (AC190) (over the state of Washington, January 10, 2008), four rudder reversals occurred, and the limit load was exceeded by 29 percent.¹¹ Finally, in an incident involving Provincial Airlines Limited (St. John’s, Newfoundland and Labrador, May 27, 2005), the pilot commanded a pedal reversal during climb-out, when the airplane entered an aerodynamic stall.¹² The loads occurring during this event were less than limit loads, but this incident is additional evidence that pedal reversals occur in service.

In 2006, the FAA sponsored a survey¹³ to better comprehend transport category pilots’ understanding and use of the rudder. This survey inquired of transport pilots from all over the world. The FAA’s analysis of the survey data found that—

- Pilots use the rudder more than FAA experts previously thought and often in ways not recommended by manufacturers.
- Pilots make erroneous rudder pedal inputs, some of which include rudder reversals.
- Even after specific training, many pilots are not aware that they should not make rudder reversals, even below V_A . Over the last several years, training and changes to airplane flight manuals directed the pilot to avoid making cyclic

control inputs. The rudder reversals that caused the AC190 incident in 2008 and the Provincial Airlines Limited incident in 2005 occurred despite these efforts.

Pilots in airplane upset situations (e.g., wake vortex encounters) may revert to prior training and make sequential rudder reversals. Based on information from the survey, the FAA expects that repeated rudder reversals will continue to occur despite flightcrew training, because training alone cannot address all potential flightcrew behaviors that can lead to such inputs. For example, the relationship between rudder inputs and the roll and yaw responses of the airplane can become confusing to pilots. This is particularly true with the large yaw and roll rates that result from large rudder inputs, combined with naturally-occurring delays between pedal input and airplane response that result from transport airplane flight dynamics. Such confusion might lead pilots to command repeated rudder reversals.

B. National Transportation Safety Board (NTSB) Recommendation

Following the AA587 accident, the NTSB submitted safety recommendations to the FAA. The NTSB stated, “[f]or airplanes with variable stop rudder travel limiter systems, protection from dangerous structural loads resulting from sustained alternating large rudder pedal inputs can be achieved by reducing the sensitivity of the rudder control system (for example, by increasing the pedal forces), which would make it harder for pilots to quickly perform alternating full rudder inputs.”¹⁴ In Safety Recommendation A–04–056,¹⁵ the NTSB recommended the FAA modify part 25 to “include a certification standard that will ensure safe handling qualities in the yaw axis throughout the flight envelope, including limits for rudder pedal sensitivity.” This final rule addresses this recommendation and will reduce the likelihood of an event that would be similar to the AA587 accident.

C. Aviation Rulemaking Advisory Committee (ARAC) Activity

In 2011, the FAA tasked the ARAC to consider the need to add a new flight maneuver load condition to part 25, subpart C, that would “ensure airplane structural capability in the presence of

⁴ V_D is the design diving speed: the maximum speed at which the airplane is certified to fly. See 14 CFR 1.2 and 25.335.

⁵ A rudder “reversal” is a continuous, pilot-commanded control movement starting from control displacement in one direction followed by control displacement in the opposite direction.

⁶ NTSB Aircraft Accident Report NTSB/AAR–04/04, “In-flight Separation of Vertical Stabilizer, American Airlines Flight 587, Airbus Industrie A300–605R, N14053, Belle Harbor, New York, November 12, 2001,” dated October 26, 2004, <https://www.nts.gov/investigations/AccidentReports/Reports/AAR0404.pdf>, p. 160.

⁷ FAA Aviation Rulemaking Advisory Committee. Flight Controls Harmonization Working Group. “Rudder Pedal Sensitivity/Rudder Reversal Recommendation Report,” November 7, 2013. (ARAC Rudder Reversal Report). This Report identifies four notable rudder events to which the FAA adds the Interflug incident discussed in the NTSB AA587 Report.

⁸ NTSB Aircraft Accident Report NTSB/AAR–04/04, pp. 106–109.

⁹ NTSB Aircraft Accident Report NTSB/AAR–04/04, pp. 104.

¹⁰ NTSB Aircraft Accident Report NTSB/AAR–04/04, pp. 38–39.

¹¹ Transportation Safety Board of Canada (TSB) Aviation Investigation Report A08W0007, “Encounter with Wake Turbulence,” <https://www.bst-tsb.gc.ca/eng/rapports-reports/aviation/2008/A08W0007/A08W0007.html>.

¹² TSB Aviation Investigation Report A05A0059, “Stall and Loss of Control During Climb,” <https://www.bst-tsb.gc.ca/eng/rapports-reports/aviation/2005/a05a0059/a05a0059.html>.

¹³ Report No. DOT/FAA/AM–10/14 (see footnote 3), OMB Control No. 2120–0712.

¹⁴ NTSB Safety Recommendation, November 10, 2004, at p. 2. This document is available in the docket and at http://www.nts.gov/safety/safety-recs/RecLetters/A04_56_62.pdf.

¹⁵ NTSB Safety Recommendation A–04–056, dated November 10, 2004, is available in the docket and at http://www.nts.gov/safety/safety-recs/RecLetters/A04_56_62.pdf.

rudder reversals” and increasing sideslip angles (yaw angles) at airspeeds up to V_D . The FAA also tasked the ARAC to consider whether other airworthiness standards would address this concern, such as pedal characteristics that would discourage pilots from making rudder reversals.¹⁶ The ARAC delegated this task to the Transport Airplane and Engine subcommittee, which assigned it to the Flight Controls Harmonization Working Group (FCHWG) of the subcommittee.

The ARAC FCHWG completed its report in November 2013.¹⁷ ARAC approved the report and submitted it to the FAA on December 30, 2013. One of the recommendations of the ARAC FCHWG Rudder Reversal Report was to require transport category airplanes to be able to withstand safely the loads imposed by three rudder reversals.¹⁸ This final rule adopts that recommendation. The ARAC report indicates that requiring transport category airplanes to operate safely with the vertical stabilizer loads imposed by three full-pedal reversals accounts for most of the attainable safety benefits. With more than three rudder reversals, the ARAC FCHWG found little increase in vertical stabilizer loads.

The report’s findings and recommendations guided the formation of the FAA’s Yaw Maneuver Conditions—Rudder Reversals notice of proposed rulemaking (NPRM) (83 FR 32087, July 16, 2018) and this final rule.

D. Summary of the NPRM

On July 16, 2018, the FAA published an NPRM that proposed to add a new regulation to address rudder reversal conditions on transport category airplanes (83 FR 32087). The FAA intended that this new requirement would prevent structural failure of the rudder and vertical stabilizer caused by reversals of the rudder pedals. Thus, the FAA proposed to require that airplanes

be able to withstand the structural loads caused by three full reversals (doublets) of the rudder pedals. The FAA proposed to apply the requirement only to airplanes with powered rudder control surfaces.

E. Rulemaking by the European Union Aviation Safety Agency (EASA)

On November 5, 2018, EASA published amendment 22 to Certification Specifications 25 (CS-25). This amendment included a new regulation, CS 25.353, “Rudder control reversal conditions,” as well as Acceptable Means of Compliance 25.353. EASA’s new regulation is similar to this final rule except that the final rule adopted by the FAA applies only to airplanes that have a powered rudder control surface or surfaces.

F. Advisory Material

FAA Advisory Circular (AC) 25.353–1, “Rudder Control Reversal Conditions,” which accompanies this rule, provides guidance on acceptable means, but not the only means, of showing compliance with § 25.353. AC 25.353–1 is available in the public docket for this rulemaking.

III. Discussion of Public Comments and Final Rule

The FAA received comments from the NTSB, Airline Pilots Association, International (ALPA), ATR, Crew Systems, Textron Aviation, Airbus, The Boeing Company, and Bombardier Aerospace. The NTSB, ALPA, ATR, and Crew Systems supported the proposal and did not suggest changes to it. Textron Aviation and Airbus requested that the rule specify a single, full-pedal command followed by one rudder reversal and return to neutral, rather than three rudder reversals as proposed in the NPRM. Those two companies, along with Boeing, also requested other changes, as described in this section of the preamble. Bombardier Aerospace commented on the rule’s cost, suggesting that the FAA issue guidance to limit the rule’s applicability.

A. Necessity of Three Reversals

In the NPRM, the FAA proposed a design load condition that consists of a single, full-pedal command followed by three full-pedal reversals and return to neutral. Two airplane manufacturers, Textron Aviation and Airbus, requested that the rule instead specify a single, full-pedal command followed by one rudder reversal and return to neutral. These companies believed this condition was more appropriate given the rarity of rudder reversals and the uniqueness of the AA587 accident

airplane. They advocated that a single, full-pedal command followed by one rudder reversal and return to neutral would cover all other known incidents, stated their concern that the proposed criteria could result in weight penalties or detrimental system changes, and proposed that enhanced flightcrew training would be more effective than designing for multiple rudder reversals.

The FAA emphasizes that while rudder reversals are rare, they can lead to serious consequences. The AA587 accident and four other accidents and incidents involved multiple rudder reversals, some of which were full-pedal reversals. Since these accidents occurred, modern airplane design requirements have not changed in a manner that would deter pilots from making such multiple reversals. Additionally, based on information received in response to the 2006 pilot survey, the FAA found that some respondents reported making rudder pedal reversals (cyclic rudder-pedal commands).¹⁹ Moreover, an analysis in the ARAC report shows that loads would continue to increase upon subsequent pedal reversals. Therefore, a single, full-pedal command followed by one full-pedal reversal and return to neutral would not represent the conditions resulting from multiple full-pedal reversals that may result in injuries to occupants or a structural failure that jeopardizes continued safe flight and landing of the airplane. Data from all manufacturers on the ARAC FCHWG showed that after three full-pedal reversals, the maximum sideslip angle does not increase significantly. Maximum sideslip angle causes the maximum loads on the vertical stabilizer; therefore, three full-pedal reversals result in a load condition that accounts for most of the attainable safety benefits.

Regarding the concern that the proposed multiple reversal condition could result in potential weight penalties or detrimental system changes in future designs, as discussed in the NPRM preamble, the FAA expects that most applicants will use control laws to comply with this rule. Because manufacturers typically implement control laws through systems and software, use of this solution to comply would result in little to no incremental cost in the form of weight, equipment, maintenance, or training for those airplanes with powered rudder control surfaces.

Based on information from the 2006 survey, the FAA does not agree with

¹⁶ The FAA published this notice of ARAC tasking in the **Federal Register** on March 28, 2011. *Aviation Rulemaking Advisory Committee; Transport Airplane and Engine Issues—New Task*, 76 FR 17183.

¹⁷ ARAC FCHWG Recommendation Report, “Rudder Pedal Sensitivity/Rudder Reversal,” dated November 7, 2013, is available in the Docket and at https://www.faa.gov/regulations_policies/rulemaking/committees/documents/media/TAEfch-rpsrr-3282011.pdf.

¹⁸ One member of the ARAC FCHWG did not support any rulemaking. The remaining members of the ARAC FCHWG found that a yaw maneuver load condition would be the optimal way to protect the airplane from the excessive loads that can result from multiple rudder reversals because they found systems solutions, such as fly-by-wire systems and manual systems with appropriate yaw dampers, to be too design-prescriptive. The members of the ARAC FCHWG held divided opinions, however, on what the load condition should be.

¹⁹ Report No. DOT/FAA/AM–10/14 at p. 14 (see footnote 3).

Textron and Airbus that enhanced flight crew training would be more effective than designing for multiple full-pedal reversals. As described earlier in the preamble, the FAA's analysis of the survey found that even after specific training, many pilots are not aware that they should not make full-pedal reversals, even below V_A . While training and changes to airplane flight manuals directed the pilot to avoid making cyclic control inputs, the pedal reversals that caused the AC190 incident in 2008 and the Provincial Airlines Limited incident in 2005 occurred despite these efforts.

Moreover, in transport category airplanes, rudder inputs are generally limited to aligning the airplane with the runway during crosswind landings and controlling engine-out situations, which occur predominately at low speeds. At high speeds, the pilot normally directly rolls the airplane using the ailerons.²⁰ If the pilot does use the rudder to control the airplane at high speeds, there will be a significant phase lag between the rudder input and the roll response because the roll response is a secondary effect of the yawing moment generated by the rudder.²¹ The roll does not result from the rudder input directly. Even if the rudder is subsequently deflected in the opposite direction (rudder reversal), the airplane can continue to roll and yaw in one direction before reversing because of the phase lag. The relationship between rudder inputs and the roll and yaw response of the airplane can become confusing to pilots, particularly with the large yaw and roll rates that would result from large rudder inputs, causing the pilots to input multiple rudder reversals.

For the foregoing reasons, the FAA has determined that a three full-pedal reversal condition is necessary to account for the effects of multiple rudder reversals that the FAA expects to occur in service. The FAA adopts this aspect of the proposal without change.

B. Applicability

Airbus requested that the rule apply only to new aircraft designs; Bombardier requested that the rule apply only to new airplanes or to airplanes where the rudder system has been significantly modified. The FAA agrees in part with the comments regarding applicability. This final rule requires that new airplane designs meet the new standards. Where an applicant proposes

a change to a previously approved type design, § 21.101, "Designation of applicable regulations," requires an assessment to determine the amendment level (version) of each regulation to be applied to that type design change. The FAA would determine under the provisions of § 21.101 whether this final rule would be applied to a changed airplane design.

Additionally, Airbus requested that the rule apply to all transport category airplanes, including those with unpowered control surfaces. Similarly, the corresponding and recently adopted European Union Aviation Safety Agency (EASA) rule, CS 25.353, applies to all airplanes, including those with unpowered control surfaces. However, in the NPRM, the FAA proposed to apply this rule only to airplanes with a powered control surface or surfaces.

A powered rudder control surface is one in which the force required to deflect the surface against the airstream is generated or augmented by hydraulic or electric systems. In contrast, an unpowered rudder control surface is one for which the force required to deflect the surface against the airstream is transmitted from the pilot's rudder pedal directly through mechanical means, without any augmentation from hydraulic or electrical systems. Powered rudder control systems include fly-by-wire (FBW) and hydro-mechanical systems, while unpowered rudder control systems are also known as mechanical systems. Incorporation of a powered yaw damper into an otherwise unpowered rudder control system does not constitute a powered rudder control surface, for the purpose of this rule.

Small business jets that typically have unpowered rudder control surfaces provide immediate feedback to their flightcrews in response to yaw inputs. Those flightcrews are, therefore, less likely to execute inappropriate rudder pedal reversals. The FAA reviewed accident and incident records and found no events in which pilots commanded inappropriate full-pedal reversals on airplanes with unpowered rudder control surfaces. Also, the use of airplanes with unpowered rudder control surfaces is diminishing in the transport category fleet. The only transport category airplane model in U.S. production with an unpowered rudder control surface also has a yaw damper. The normal operation of the yaw damper would be adequate to reduce yaw overshoot loads from full-pedal reversals.

As explained in the NPRM and this final rule, the safety benefit of expanding this rule to airplanes with unpowered control surfaces does not

outweigh the potentially higher costs of implementation. The FAA may consider the requested change later if data or information become available to indicate that either the safety case has changed or implementation costs have decreased.

C. Load Condition Requirements

Airbus and Boeing requested the FAA include in the rule the following text: "Flaps (or flaperons or any other aerodynamic devices when used as flaps) and slats extended configurations are also to be considered if they are used in en route conditions." Including this provision would require applicants to evaluate the rudder reversal conditions with flaps and other devices extended, if the airplane uses those devices in en route conditions.²² Airbus also requested that the rule include the following text: "Unbalanced aerodynamic moments about the center of gravity must be reacted in a rational or conservative manner considering the airplane inertia forces." This language specifies how the applicant sums the various forces when analyzing the rudder reversal conditions. Both commenters requested the FAA include these requirements in the final rule to be consistent with the ARAC FCHWG report and to harmonize with the EASA regulation.

The FAA agrees that the additions identified by commenters should be included in the final rule because both requirements harmonize with the EASA rule (CS 25.353) and clarify how to analyze the load conditions. The two requirements are also found in other part 25 regulations, including §§ 25.345 and 25.351. The FAA notes that the requirement to consider the effect of flaps and slats in en route conditions has slightly different wording than the EASA rule, but has the same meaning. As these changes simply clarify how to analyze the load conditions, they will not add additional burdens.

Airbus also requested that the airplane be able to withstand the prescribed conditions at an uppermost speed of V_C , rather than V_C/M_C , as proposed in the NPRM. The FAA disagrees with the commenter. The proposed rule included V_C/M_C because airplanes have defined limitations for both V_C and M_C . However, no substantive difference between the two exists because each value of V_C has a corresponding value of M_C . As a result, using V_C/M_C is appropriate in this rule.

²⁰ An aileron is a hinged control surface on the trailing edge of the wing of a fixed-wing aircraft, one aileron per wing.

²¹ The yaw axis is defined to be perpendicular to the wings and to the normal line of flight. A yaw movement is a change in the direction of the aircraft to the left or right around the yaw axis.

²² En route conditions means the conditions occurring during any phase of flight after initial climb and before the final descent and landing phase.

D. Warning Monitors

Airbus requested that the rule allow an applicant to show compliance via implementing monitors that would warn the pilot of inappropriate rudder use. The FAA does not agree with this comment. Pilot-commanded rudder reversals have occurred during high workload and conditions that are often startling. Thus, depending on the pilot to react appropriately to a warning under such conditions would not provide the equivalent safety benefit as the load conditions in this final rule and would be inconsistent with the EASA regulation.

E. Miscellaneous Modifications

As previously noted, EASA published its regulation, CS 25.353, on November 5, 2018, a few months after the FAA issued the NPRM upon which this final rule is based. This final rule contains minor modifications to harmonize with the EASA standard. These modifications are in addition to those described earlier in the final rule (C. Load Condition Requirements). These modifications include:

(1) The proposed rule specified that the applicant evaluate the rudder reversal conditions “from V_{MC} or the highest airspeed for which it is possible to achieve maximum rudder deflection at zero sideslip, whichever is greater, up to V_C/M_C .” This final rule establishes the speed range as “ V_{MC} to V_C/M_C .” This is simpler to apply because it does not require an additional calculation of “the highest speed for which it is possible . . .” and it is consistent with the current rudder maneuver condition required by § 25.351. (Section 25.351 prescribes the speed range as V_{MC} to V_D .)

(2) This final rule provides that any permanent deformation resulting from the specified ultimate load conditions must not prevent continued safe flight and landing. This requirement is necessary because this final rule, unlike most design load conditions codified in part 25, contains only an “ultimate” load requirement, and does not contain a “limit” load requirement. Design loads are typically expressed in terms of limit loads, which are then multiplied by a factor of safety, usually 1.5, to determine ultimate loads. The airplane structure must be able to withstand limit loads without detrimental permanent deformation and ultimate loads without failure in accordance with § 25.305. Because this rule does not include a limit load requirement, it is necessary to require that no detrimental permanent deformation occur at ultimate load (deformation that would

prevent continued safe flight and landing). This requirement is also in the corresponding EASA regulation, CS 25.353.

(3) The proposed rule specified that the “rudder control is suddenly displaced” in evaluating the ultimate loads that result from the yaw maneuver conditions identified in the proposal. This final rule, however, specifies that the “rudder control is suddenly and fully displaced as limited by the control system or control surface stops.” The term “fully” makes it clear that full displacement of the rudder pedal is required. The phrase “as limited by the control system or control surface stops” further clarifies the requirement by indicating that the conditions may be conducted using rudder control system limiting hardware to establish the reversal loads. Furthermore, the aforementioned requirements are consistent with § 25.351.

IV. Regulatory Notices and Analyses

Changes to Federal regulations must undergo several economic analyses. First, Executive Orders 12866 and 13563 direct that each Federal agency shall propose or adopt a regulation only upon a reasoned determination that the benefits of the intended regulation justify its costs. Second, the Regulatory Flexibility Act of 1980 (Pub. L. 96–354), as codified in 5 U.S.C. 603 *et seq.*, requires agencies to analyze the economic impact of regulatory changes on small entities. Third, the Trade Agreements Act of 1979 (Pub. L. 96–39), 19 U.S.C. Chapter 13, prohibits agencies from setting standards that create unnecessary obstacles to the foreign commerce of the United States. In developing U.S. standards, the Trade Agreements Act requires agencies to consider international standards and, where appropriate, that they be the basis of U.S. standards. Fourth, the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4), as codified in 2 U.S.C. Chapter 25, requires agencies to prepare a written assessment of the costs, benefits, and other effects of proposed or final rules that include a Federal mandate likely to result in the expenditure by State, local, or tribal governments, in the aggregate, or by the private sector, of \$100 million or more annually (adjusted for inflation with base year of 1995). This portion of the preamble summarizes the FAA’s analysis of the economic impacts of this final rule.

In conducting these analyses, the FAA has determined that this final rule has benefits that justify its costs and is not a “significant regulatory action” as defined in section 3(f) of Executive Order 12866. The final rule is also not

“significant” as defined in DOT’s rulemaking procedures. The final rule will not have a significant economic impact on a substantial number of small entities, will not create unnecessary obstacles to the foreign commerce of the United States, and will not impose an unfunded mandate on State, local, or tribal governments, or on the private sector by exceeding the threshold identified previously.

A. Regulatory Evaluation

1. Background and Statement of Need

The genesis of this final rule is the crash of American Airlines Flight 587 (AA587), near Queens, New York, on November 12, 2001, resulting in the death of all 260 passengers and crew aboard, and the death of five persons on the ground. The airplane was destroyed by impact forces and a post-crash fire.

The NTSB found that the probable cause of the accident was “the in-flight separation of the vertical stabilizer [airplane fin] as a result of loads above ultimate design created by the first officer’s unnecessary and excessive rudder pedal inputs.”²³ Ultimate loads on the airplane structure are the limit loads (1.0) multiplied by a safety factor, usually 1.5 (as for the vertical stabilizer). An airplane is expected to experience a limit load once in its lifetime and is never expected to experience an ultimate load.²⁴ For the AA587 accident, loads exceeding ultimate loads ranged from 1.83 to 2.14 times the limit load on the vertical stabilizer,²⁵ as a result of four, full, alternating rudder inputs known as “rudder reversals.”

Significant rudder reversal events are unusual in the history of commercial airplane flight, having occurred during five notable accidents and incidents, with the AA587 accident being the only catastrophic accident resulting from rudder reversals.²⁶ Ultimate loads were exceeded in two of the other notable rudder reversal events: an incident involving Interflug (Moscow, February

²³ NTSB Aircraft Accident Report NTSB/AAR–04/04, “In-flight Separation of Vertical Stabilizer, American Airlines Flight 587, Airbus Industrie A300–605R, N14053, Belle Harbor, New York, November 12, 2001” at 160 (Oct. 26, 2004), available at <https://www.ntsb.gov/investigations/AccidentReports/Reports/AAR0404.pdf>.

²⁴ NTSB Aircraft Accident Report NTSB/AAR–04/04, p. 31, n. 53.

²⁵ NTSB Aircraft Accident Report NTSB/AAR–04/04, p. 104.

²⁶ FAA Aviation Rulemaking Advisory Committee. Flight Controls Harmonization Working Group. “Rudder Pedal Sensitivity/Rudder Reversal Recommendation Report,” November 7, 2013. (ARAC Rudder Reversal Report). This Report identifies four notable rudder events to which the FAA adds the Interflug incident discussed in the NTSB AA587 Report.

11, 1991) and an accident involving American Airlines Flight 903 (AA903) (near West Palm Beach, Florida, May 12, 1997).²⁷ The Interflug incident involved multiple rudder reversals, and loads of 1.55 and 1.35 times the limit load were recorded. For the AA903 incident, eight rudder reversals occurred, and a load of 1.53 times the limit load was recorded.²⁸ A catastrophe similar to AA587 was averted in these two events only because the vertical stabilizers were stronger than required by design standards.²⁹ In a fourth event—Air Canada Flight 190 (AC190) (over the state of Washington, January 10, 2008)—four rudder reversals occurred, and the limit load was exceeded by 29 percent.³⁰ The fifth event was a de Havilland DHC-8-100 (Dash 8) (St. John's, Newfoundland and Labrador, May 27, 2005) in which the pilot commanded a pedal reversal during climb-out, when the airplane entered an aerodynamic stall.³¹ There were no injuries, and the airplane was not damaged. The ARAC FCHWG determined the loads occurring during this event were less than limit load, but this incident is additional evidence that pedal reversals occur in service.

In transport category airplanes, rudder inputs are generally limited to aligning the airplane with the runway during crosswind landings and controlling engine-out situations, which occur predominately at low speeds. At high speeds, the pilot normally directly rolls the airplane using the ailerons.³² If the pilot does use the rudder to control the airplane at high speeds, there will be a significant phase lag between the rudder input and the roll response because the

roll response is a secondary effect of the yawing moment generated by the rudder.³³ The roll does not result from the rudder input directly. Even if the rudder is subsequently deflected in the opposite direction (rudder reversal), the airplane can continue to roll and yaw in one direction before reversing because of the phase lag. The relationship between rudder inputs and the roll and yaw response of the airplane can become confusing to pilots, particularly with the large yaw and roll rates that would result from large rudder inputs, causing the pilots to input multiple rudder reversals.

Following the AA587 accident in November 2004, the NTSB issued Safety Recommendation A-04-56, recommending that the FAA modify part 25 “to include a certification standard that will ensure safe handling qualities in the yaw axis throughout the flight envelope”³⁴ In 2011, the FAA tasked ARAC to consider the need for rulemaking to address the rudder reversal issue. ARAC delegated this task to the Transport Airplane and Engine subcommittee, which assigned it to the FCHWG. One of the recommendations of the ARAC FCHWG Rudder Reversal Report, issued on November 7, 2013, was to require transport category airplanes to be able to withstand safely the loads imposed by three rudder reversals. This final rule adopts that recommendation. The ARAC report indicates that requiring transport category airplanes to operate safely with the vertical stabilizer loads imposed by three full-pedal reversals accounts for most of the attainable safety benefits. With more than three rudder reversals, the FCHWG found little increase in vertical stabilizer loads.

2. Impacts of This Final Rule

Since the catastrophic AA587 accident, the FAA has requested that applicants for new type certificates show that their designs are capable of continued safe flight and landing after experiencing repeated rudder reversals. For airplanes with fly-by-wire (FBW) systems, manufacturers have been able to show capability by means of control laws, incorporated through software

changes, adding no weight and imposing no additional maintenance cost to the airplanes. Many, if not all, of these designs have demonstrated tolerance to three or more rudder reversals. Aside from converting to an FBW or hydro-mechanical system, alternatives available to manufacturers specializing in airplane designs with mechanical rudders include increasing the reliability of the yaw damper and strengthening the airplane vertical stabilizer.

To estimate the cost of the final rule, the FAA reviewed unit cost estimates from U.S. airplane manufacturers and incorporated these estimates into an airplane life cycle model. The FAA received one estimate for large part 25 airplanes and two estimates for small part 25 airplanes (*i.e.*, business jets).

A manufacturer specializing in mechanical rather than FBW rudder systems provided a business jet estimate that reflects significantly higher compliance costs. This manufacturer's most cost-efficient approach to addressing the requirement—although high in comparison to manufacturers that use FBW systems exclusively—is to comply with a strengthened vertical stabilizer. The cost of complying with a more reliable yaw damper was higher than strengthening the vertical stabilizer, and higher still if complying by converting to an FBW rudder system for new models.

As a result of these high costs and the reasons set forth in the NPRM and the preceding “Discussion of Comments and Final Rule,” this final rule will not apply to airplanes with unpowered (mechanical) rudder control surfaces. An unpowered rudder control surface is one whose movement is affected through mechanical means, without any augmentation (for example, from hydraulic or electrical systems). Accordingly, the final rule does not apply to models with mechanical rudder control systems, but applies only to models with FBW or hydro-mechanical rudder systems.

The FAA estimates the costs of the final rule using unit cost per model estimates from industry for FBW models and the agency's estimates of the number of new large airplane and business jet certifications with FBW rudder systems in the ten years after the effective date of the final rule. These estimates are shown in Table 1.

²⁷ NTSB Aircraft Accident Report NTSB/AAR-04/04, pp. 106–109; *see also* NTSB Aircraft Accident Report AA903 (NTSB DCA97MA049).

²⁸ NTSB Aircraft Accident Report NTSB/AAR-04/04, pp. 104; *Report on the Investigation of the Abnormal Behavior of an Airbus A310-304 Aircraft on 11.02.199 at Moscow*, Air Accident Investigation Department of the German Federal Office of Aviation, Reference 6X002-0/91.

²⁹ NTSB Aircraft Accident Report NTSB/AAR-04/04, pp. 38–39.

³⁰ Transportation Safety Board of Canada (TSB) Aviation Investigation Report A08W0007, “Encounter with Wake Turbulence,” <https://www.bst-tsb.gc.ca/eng/rapports-reports/aviation/2008/08W0007/A08W0007.html>.

³¹ TSB Aviation Investigation Report A05A0059, “Stall and Loss of Control During Climb,” <https://www.bst-tsb.gc.ca/eng/rapports-reports/aviation/2005/a05a0059/a05a0059.html>.

³² An aileron is a hinged control surface on the trailing edge of the wing of a fixed-wing aircraft, one aileron per wing.

³³ The yaw axis is defined to be perpendicular to the wings and to the normal line of flight. A yaw movement is a change in the direction of the aircraft to the left or right around the yaw axis.

³⁴ NTSB Safety Recommendation A-04-56 (Nov. 10, 2004), available at https://www.ntsb.gov/safety/safety-recs/RecLetters/A04_56_62.pdf.

TABLE 1—COST ESTIMATED FOR FINAL RULE (\$ 2016)

	Cost per model	Number of new FBW models (10 yrs)	Costs
Large Airplanes	\$300,000	2	\$600,000
Business Jets	235,000	2	470,000
Total Costs	1,070,000

With these cost estimates, the FAA concludes the final rule will entail minimal cost, with expected net safety benefits from the reduced risk of rudder reversal accidents.

B. Regulatory Flexibility Determination

The Regulatory Flexibility Act of 1980 (Pub. L. 96–354) (RFA) establishes “as a principle of regulatory issuance that agencies shall endeavor, consistent with the objectives of the rule and of applicable statutes, to fit regulatory and informational requirements to the scale of the businesses, organizations, and governmental jurisdictions subject to regulation. To achieve this principle, agencies are required to solicit and consider flexible regulatory proposals and to explain the rationale for their actions to assure that such proposals are given serious consideration.” The RFA covers a wide range of small entities, including small businesses, not-for-profit organizations, and small governmental jurisdictions.

Agencies must perform a review to determine whether a rule will have a significant economic impact on a substantial number of small entities. If the agency determines that it will, the agency must prepare a regulatory flexibility analysis as described in the RFA. However, if an agency determines that a rule is not expected to have a significant economic impact on a substantial number of small entities, section 605(b) of the RFA provides that the head of the agency may so certify and a regulatory flexibility analysis is not required. The certification must include a statement providing the factual basis for this determination, and the reasoning should be clear.

As noted above, because manufacturers with FBW rudder systems have been able to show compliance by means of low-cost changes to control laws incorporated through software changes, the FAA estimates the costs of this final rule to be minimal. Therefore, pursuant to section 605(b), the head of the FAA certifies that this final rule will not have a significant economic impact on a substantial number of small entities.

C. International Trade Impact Assessment

The Trade Agreements Act of 1979 (Pub. L. 96–39) prohibits Federal agencies from establishing standards or engaging in related activities that create unnecessary obstacles to the foreign commerce of the United States. Pursuant to this Act, the establishment of standards is not considered an unnecessary obstacle to the foreign commerce of the United States, so long as the standard has a legitimate domestic objective, such as the protection of safety, and does not operate in a manner that excludes imports that meet this objective. The statute also requires consideration of international standards and, where appropriate, that they be the basis for U.S. standards.

The FAA has assessed the effect of this final rule and determined that its purpose is to protect the safety of U.S. civil aviation. Therefore, the final rule is in compliance with the Trade Agreements Act.

D. Unfunded Mandates Assessment

Title II of the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4) requires each Federal agency to prepare a written statement assessing the effects of any Federal mandate in a proposed or final agency rule that may result in an expenditure of \$100 million or more (in 1995 dollars) in any one year by State, local, and tribal governments, in the aggregate, or by the private sector; such a mandate is deemed to be a “significant regulatory action.” The FAA currently uses an inflation-adjusted value of \$155.0 million in lieu of \$100 million.

This final rule does not contain such a mandate. Therefore, the requirements of Title II of the Act do not apply.

E. Paperwork Reduction Act

The Paperwork Reduction Act of 1995 (44 U.S.C. 3507(d)) requires that the FAA consider the impact of paperwork and other information collection burdens imposed on the public. The FAA has determined that there is no new requirement for information

collection associated with this final rule.

F. International Compatibility

In keeping with U.S. obligations under the Convention on International Civil Aviation, it is FAA policy to conform to International Civil Aviation Organization (ICAO) Standards and Recommended Practices to the maximum extent practicable. The FAA has determined that there are no ICAO Standards and Recommended Practices that correspond to these regulations.

G. Environmental Analysis

FAA Order 1050.1F, Environmental Impacts: Policies and Procedures, identifies FAA actions that are categorically excluded from preparation of an environmental assessment or environmental impact statement under the National Environmental Policy Act in the absence of extraordinary circumstances. The FAA has determined this rulemaking action qualifies for the categorical exclusion identified in paragraph 5–6.6 for regulations and involves no extraordinary circumstances.

V. Executive Order Determinations

A. Executive Order 13132, Federalism

The FAA has analyzed this final rule under the principles and criteria of Executive Order 13132, Federalism. The agency determined that this action will not have a substantial direct effect on the States, or the relationship between the Federal Government and the States, or on the distribution of power and responsibilities among the various levels of government, and, therefore, does not have Federalism implications.

B. Executive Order 13211, Regulations that Significantly Affect Energy Supply, Distribution, or Use

The FAA analyzed this final rule under Executive Order 13211, Actions Concerning Regulations that Significantly Affect Energy Supply, Distribution, or Use (May 18, 2001). The agency has determined that it is not a “significant energy action” under the executive order and it is not likely to

have a significant adverse effect on the supply, distribution, or use of energy.

C. Executive Order 13609, International Cooperation

Executive Order 13609, Promoting International Regulatory Cooperation, (77 FR 26413, May 4, 2012) promotes international regulatory cooperation to meet shared challenges involving health, safety, labor, security, environmental, and other issues and reduce, eliminate, or prevent unnecessary differences in regulatory requirements. The FAA has analyzed this action under the policy and agency responsibilities of Executive Order 13609. The agency has determined that this action would eliminate differences between U.S. aviation standards and those of other civil aviation authorities by harmonizing with the corresponding EASA requirement. As noted above, EASA published its corresponding regulation, CS 25.353, on November 5, 2018. This final rule harmonizes with that standard, with the exception that this rule excludes airplanes that have an unpowered rudder control surface(s).

VI. How to Obtain Additional Information

A. Rulemaking Documents

An electronic copy of a rulemaking document may be obtained by using the internet—

1. Search the Federal eRulemaking Portal (<http://www.regulations.gov>);
2. Visit the FAA's Regulations and Policies web page at http://www.faa.gov/regulations_policies/; or
3. Access the Government Printing Office's web page at <http://www.gpo.gov/fdsys/>.

Copies may also be obtained by sending a request (identified by notice, amendment, or docket number of this rulemaking) to the Federal Aviation Administration, Office of Rulemaking, ARM-1, 800 Independence Avenue SW, Washington, DC 20591, or by calling (202) 267-9680.

B. Comments Submitted to the Docket

Comments received may be viewed by going to <http://www.regulations.gov> and following the online instructions to search the docket number for this action. Anyone is able to search the electronic form of all comments received into any of the FAA's dockets by the name of the individual submitting the comment (or signing the comment, if submitted on behalf of an association, business, labor union, etc.).

C. Small Business Regulatory Enforcement Fairness Act

The Small Business Regulatory Enforcement Fairness Act (SBREFA) of 1996 (Pub. L. 104-121) (set forth as a note to 5 U.S.C. 601) requires the FAA to comply with small entity requests for information or advice about compliance with statutes and regulations within its jurisdiction. A small entity with questions regarding this document may contact its local FAA official or the person listed under the **FOR FURTHER INFORMATION CONTACT** heading at the beginning of the preamble. To find out more about SBREFA on the internet, visit http://www.faa.gov/regulations_policies/rulemaking/sbre_act/.

List of Subjects in 14 CFR Part 25

Aircraft, Aviation safety, Reporting and recordkeeping requirements.

The Amendment

In consideration of the foregoing, the Federal Aviation Administration amends chapter I of title 14, Code of Federal Regulations as follows:

PART 25—AIRWORTHINESS STANDARDS: TRANSPORT CATEGORY AIRPLANES

- 1. The authority citation for part 25 continues to read as follows:

Authority: 49 U.S.C. 106(f), 106(g), 40113, 44701, 44702 and 44704.

- 2. Add § 25.353 under the undesignated center heading “Flight Maneuver and Gust Conditions” to read as follows:

§ 25.353 Rudder control reversal conditions.

Airplanes with a powered rudder control surface or surfaces must be designed for loads, considered to be ultimate, resulting from the yaw maneuver conditions specified in paragraphs (a) through (e) of this section at speeds from V_{MC} to V_C/M_C . Any permanent deformation resulting from these ultimate load conditions must not prevent continued safe flight and landing. The applicant must evaluate these conditions with the landing gear retracted and speed brakes (and spoilers when used as speed brakes) retracted. The applicant must evaluate the effects of flaps, flaperons, or any other aerodynamic devices when used as flaps, and slats-extended configurations, if they are used in en route conditions. Unbalanced aerodynamic moments about the center of gravity must be reacted in a rational or conservative manner considering the airplane inertia forces. In computing the loads on the airplane, the yawing velocity may be

assumed to be zero. The applicant must assume a pilot force of 200 pounds when evaluating each of the following conditions:

(a) With the airplane in unaccelerated flight at zero yaw, the flightdeck rudder control is suddenly and fully displaced to achieve the resulting rudder deflection, as limited by the control system or the control surface stops.

(b) With the airplane yawed to the overswing sideslip angle, the flightdeck rudder control is suddenly and fully displaced in the opposite direction, as limited by the control system or control surface stops.

(c) With the airplane yawed to the opposite overswing sideslip angle, the flightdeck rudder control is suddenly and fully displaced in the opposite direction, as limited by the control system or control surface stops.

(d) With the airplane yawed to the subsequent overswing sideslip angle, the flightdeck rudder control is suddenly and fully displaced in the opposite direction, as limited by the control system or control surface stops.

(e) With the airplane yawed to the opposite overswing sideslip angle, the flightdeck rudder control is suddenly returned to neutral.

Issued under authority provided by 49 U.S.C. 106(f), and 44701(a) in Washington, DC, on or about November 16, 2022.

Billy Nolen,

Acting Administrator.

[FR Doc. 2022-25291 Filed 11-21-22; 8:45 am]

BILLING CODE 4910-13-P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 47

[Docket No. FAA-2022-1514; Amdt. No. 47-33]

RIN 2120-AL45

Increase the Duration of Aircraft Registration

AGENCY: Federal Aviation Administration (FAA), U.S. Department of Transportation (DOT).

ACTION: Direct final rule; request for comments.

SUMMARY: The FAA is extending the duration of aircraft registration certificates from three years to seven years. Initial Certificates of Aircraft Registration will expire seven years from the month issued. In addition, the FAA is applying this amendment to all aircraft currently registered under existing FAA regulations governing

aircraft registration, which will extend valid Certificates of Aircraft Registration to a seven-year duration. This rulemaking also makes other minor revisions to rules related to internal FAA registration processes.

DATES: This direct final rule will become effective January 23, 2023.

Send comments on or before December 22, 2022. If the FAA receives an adverse comment, the FAA will advise the public by publishing a document in the **Federal Register** before the effective date of this direct final rule. That document may withdraw the direct final rule in whole or in part.

ADDRESSES: Send comments identified by docket number *FAA-2022-1514* using any of the following methods:

- *Federal eRulemaking Portal:* Go to <http://www.regulations.gov> and follow the online instructions for sending your comments electronically.

- *Mail:* Send comments to Docket Operations, M-30; U.S. Department of Transportation (DOT), 1200 New Jersey Avenue SE, Room W12-140, West Building Ground Floor, Washington, DC 20590-0001.

- *Hand Delivery or Courier:* Take comments to Docket Operations in Room W12-140 of the West Building Ground Floor at 1200 New Jersey Avenue SE, Washington, DC, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

- *Fax:* Fax comments to Docket Operations at 202-493-2251.

Privacy: In accordance with 5 U.S.C. 553(c), DOT solicits comments from the public to better inform its rulemaking process. DOT posts these comments, without edit, including any personal information the commenter provides, to www.regulations.gov, as described in the system of records notice (DOT/ALL-14 FDMS), which can be reviewed at www.dot.gov/privacy.

Docket: Background documents or comments received may be read at <https://www.regulations.gov> at any time. Follow the online instructions for accessing the docket or go to the Docket Operations in Room W12-140 of the West Building Ground Floor at 1200 New Jersey Avenue SE, Washington, DC, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

FOR FURTHER INFORMATION CONTACT: Bonnie Lefko, Program Analyst, Civil Aviation Registry, FAA Aircraft Registration Branch, Federal Aviation Administration, P.O. Box 25504, Oklahoma City, OK 73125; telephone 405-954-3131; email FAA.Aircraft.Registry@faa.gov.

SUPPLEMENTARY INFORMATION:

Table of Contents

I. Executive Summary	
II. Direct Final Rule	
III. Authority for This Rulemaking	
IV. Discussion of the Direct Final Rule	
A. Background and Purpose of Regulatory Action	
B. Implementation of Section 556 of the FAA Reauthorization Act of 2018	
C. Other Part 47 Amendments	
V. Regulatory Notices and Analyses	
A. Regulatory Evaluation	
B. Regulatory Flexibility Determination	
C. International Trade Impact Assessment	
D. Unfunded Mandates Assessment	
E. Paperwork Reduction Act	
F. International Compatibility	
G. Environmental Analysis	
VI. Executive Order Determinations	
A. Executive Order 13132, Federalism	
B. Executive Order 13211, Regulations That Significantly Affect Energy Supply, Distribution, or Use	
C. Executive Order 13609, International Cooperation	
VII. Additional Information	
A. Comments Invited	
B. Confidential Business Information	
C. Electronic Access and Filing	
D. Small Business Regulatory Enforcement Fairness Act	

List of Abbreviations Frequently Used in This Document

Application—Aircraft Registration Application, AC Form 8050-1
 Certificate—Certificate of Aircraft Registration, AC Form 8050-3
 Registry—Civil Aviation Registry, FAA Aircraft Registration Branch
 Renewal Form—Aircraft Registration Renewal Application, AC Form 8050-1B

I. Executive Summary

This rulemaking amends the duration of all Certificates of Aircraft Registration (certificates) issued under part 47 of Title 14 of the Code of Federal Regulations (14 CFR) from three years to seven years. Aircraft owners will be required to confirm their registration information and renew their certificate every seven years, unless an event or circumstance necessitates a new registration being submitted prior to the expiration of the certificate. Accordingly, this rule adds a paragraph to § 47.40 to require aircraft owners to submit new registration forms to update their certificates prior to the seven-year expiration date if the Administrator determines that their registration information is inaccurate. These amendments apply to initial and renewed certificates in accordance with § 47.40(b) and (c).

The FAA is also revising 14 CFR 47.31(c)(1) to remove the requirement that the FAA issue a letter extending the temporary authority for an aircraft to operate when a certificate of aircraft registration has not been issued or

denied within 90 days after the date the application was signed.

The FAA is also removing expired regulations pertaining to the re-registration requirement detailed in § 47.40(a) and references to re-registration in §§ 47.15(i)(1) and 47.17(a)(7). The re-registration regulations became obsolete January 1, 2014.

II. Direct Final Rule

An agency typically uses direct final rulemaking when it anticipates the rule will be noncontroversial and the agency believes it will not receive any adverse comments, and thus finds that a notice of proposed rulemaking is unnecessary.¹ The FAA has determined that this rule is suitable for direct final rulemaking. This rule alleviates burdens from owners of all aircraft registered in the United States by extending the period of registration from three years to seven years. It also alleviates burdens for owners of aircraft registered in the United States by removing the requirement that the FAA issue a letter extending the validity of aircraft registration. This rule also amends certain part 47 regulations related to agency practice and procedure, and removes requirements that have expired. The FAA has determined that this rule is suitable for direct final rulemaking as these changes are noncontroversial and the FAA does not anticipate receiving adverse comments.

The FAA acknowledges that Section 556 of Public Law 115-254 specifically contemplates issuance of a notice of proposed rulemaking (NPRM); however, this direct final rule meets the intent of Section 556 because the agency is providing notice and seeking comment prior to effectuating changes to the regulation.² Further, if the agency receives any substantive adverse comments, it would treat this rule as an NPRM or revise this rule prior to issuance of another direct final rule.

For purposes of this direct final rule, an adverse comment is one that explains (1) why the rule is inappropriate, including challenges to the rule's underlying premise or approach; or (2) why the direct final rule will be ineffective or unacceptable without a change.³ In determining whether an adverse comment necessitates withdrawal of this direct final rule, the

¹ 14 CFR 11.15; *General Rulemaking Procedures* final rule, 65 FR 50849 at 50855-56 (Aug. 21, 2000).

² See *Adoption of Recommendations*, 60 FR 43109, 43110-43111 (Aug. 18, 1995) (describing Administrative Conference of the United States, Recommendation 95-4, *Procedures for Noncontroversial and Expedited Rulemaking*).

³ 14 CFR 11.31(a).

FAA will consider whether the comment raises an issue serious enough to warrant a substantive response had it been submitted in response to publication of an NPRM. A comment recommending additional provisions to the rule will not be considered adverse unless the comment explains how this direct final rule would be ineffective without the added provisions.⁴

Under the direct final rule process, the FAA does not consider a comment to be adverse if that comment recommends an amendment to a different regulation beyond the regulation(s) in the direct final rule at issue. The FAA also does not consider a frivolous or insubstantial comment to be adverse.⁵

If the FAA receives an adverse comment during the comment period, the FAA will advise the public by publishing a document in the **Federal Register** before the effective date of the direct final rule. This document may withdraw the direct final rule in whole or in part. If the FAA withdraws a direct final rule because of an adverse comment, the FAA may incorporate the commenter's recommendation into another direct final rule or may publish a notice of proposed rulemaking.⁶

If the FAA receives no adverse comments, the FAA will publish a confirmation notice in the **Federal Register**, generally within 15 days after the comment period closes. The confirmation notice announces the effective date of the rule.⁷

III. Authority for This Rulemaking

The FAA's authority to issue rules on aviation safety is found in title 49 of the United States Code (49 U.S.C.). Section 106 of 49 U.S.C. describes the authority of the FAA Administrator. Subtitle VII of 49 U.S.C., Aviation Programs, describes in more detail the scope of the agency's authority. This rule is also promulgated pursuant to 49 U.S.C. 44101–44106 and 44110–44113, which require aircraft to be registered as a condition of operation and establish the requirements for registration and registration processes. The Registry is responsible for the registration and recordation of civil aircraft.

This rulemaking is promulgated under the authority described in 49 U.S.C. 106(f), which establishes the authority of the Administrator to promulgate regulations and rules; and 49 U.S.C. 44701(a)(5), which requires the Administrator to promote safe flight

of civil aircraft in air commerce by prescribing regulations and setting minimum standards for other practices, methods, and procedures necessary for safety in air commerce and national security.

This rule is also promulgated under the specific authority established in Sec. 556 of the FAA Reauthorization Act of 2018, Public Law 115–254, in which Congress required the FAA to initiate rulemaking to increase the duration of aircraft registrations for noncommercial general aviation aircraft to seven years and in which Congress gave the FAA the ability to require resubmission of aircraft registration applications that contain inaccurate information.

IV. Discussion of the Direct Final Rule

A. Background and Purpose of Regulatory Action

The Civil Aviation Registry, FAA Aircraft Registration Branch (Registry) is responsible for developing, maintaining, and operating the federal registration and recordation system for United States civil aircraft.

On July 20, 2010, the FAA published the Re-Registration and Renewal of Aircraft Registration final rule (Re-Registration Rule),⁸ which became effective October 1, 2010. The Re-Registration Rule established the current three-year duration for aircraft registrations. Prior to the Re-Registration Rule, aircraft registrations were of indefinite duration, which made it difficult for the FAA to maintain accurate aircraft registration information. While there was a requirement for aircraft owners to keep their registration up-to-date, the FAA found that many aircraft owners failed to update their registration information. Adopting the three-year duration for certificates created a regular process for aircraft owners to update their registration information. As explained in the Re-Registration Rule, the three-year duration for certificates was found at the time to provide the best balance between cost and improved accuracy of registration information.

The first phase of the Re-Registration Rule required each aircraft owner to re-register the aircraft within the specified six-month time period. The second phase of the Re-Registration Rule is the current renewal process. Each aircraft owner must submit a complete Renewal Form prior to the expiration of the current certificate to maintain registration. An aircraft registration not renewed prior to the expiration of its current certificate is subject to

cancellation. The Re-Registration Rule responded to the concerns of law enforcement and other government agencies related to accurate, up-to-date aircraft registration information without placing an undue burden on aircraft owners.

Section 556 of the FAA Reauthorization Act of 2018⁹ mandated the FAA initiate rulemaking to increase the duration of aircraft registrations for noncommercial general aviation aircraft to 7 years. However, as discussed in the analysis that follows, the FAA cannot distinguish between commercial and noncommercial general aviation aircraft, as that determination is dependent upon the operations being conducted by general aviation aircraft. Consequently, it is impracticable to have different durations for commercial and noncommercial general aviation aircraft registrations. Therefore, the FAA is extending the registration duration for all aircraft to 7 years.

B. Implementation of Section 556 of the FAA Reauthorization Act of 2018

This action implements Section 556. Currently, an initial registration expires three years after the last day of the month it is issued.¹⁰ A renewal certificate currently expires three years from the expiration of the previous certificate.¹¹

The FAA is amending the certificate duration period to seven years for all aircraft. The FAA does not possess a list of noncommercial general aviation aircraft. Moreover, an aircraft may operate as noncommercial general aviation on one flight and commercial aviation on another flight. Therefore, this rulemaking benefits all aircraft owners by lessening the burden and cost of renewing aircraft registration and aligning all aircraft registrations with the requirement set forth by Congress. Additionally, as discussed further in the regulatory evaluation section, the FAA determined that extending registration for only noncommercial general aviation aircraft would not be cost beneficial because there are no quantifiable or monetized benefits of not also extending the duration of certificates of commercial aircraft.

Therefore, the FAA revises § 47.40(b) and (c) to increase the duration of aircraft registration to seven years. The initial registration certificate will expire seven years after the last day of the month in which it is issued. The

⁹ Public Law 115–254.

¹⁰ The term “initial registration” refers to the certificate issued in accordance with 14 CFR 47.31.

¹¹ The term “renewal” refers to the periodic registration renewal required for any aircraft that has a certificate with an expiration.

⁴ 14 CFR 11.31(a)(1).

⁵ 14 CFR 11.31(a)(1) and (2).

⁶ 14 CFR 11.31(c).

⁷ 14 CFR 11.31(b).

⁸ 75 FR 41968.

renewal will expire seven years after the last day of the month in which it is issued. This amendment will apply to all new Certificates of Aircraft Registration issued after the effective date of this rule and Certificates of Aircraft Registration valid on the date this rule becomes effective. The duration of new registrations issued after the effective date of this direct final rule will be seven years from the date of registration; valid registrations in effect on the date of this direct final rule will be extended such that the total term of registration will be seven years from the date of issuance of the currently valid renewal, notwithstanding the expiration date on the Certificate of Aircraft Registration. See Table 1.

TABLE 1—EXPIRATION DATES FOR CERTIFICATES OF AIRCRAFT REGISTRATION IN EFFECT ON THE EFFECTIVE DATE OF THE DIRECT FINAL RULE

If the certificate was issued in—	The certificate expires in—
2019	2026
2020	2027
2021	2028
2022	2029
2023	2030

Additionally, the FAA is updating § 47.40 to include paragraph (c), which allows the Administrator to require an aircraft owner to submit a registration form and fee to update a registration at any time prior to the expiration date of the certificate if the information provided to the Registry is found to be inaccurate. This requirement is consistent with section 556(b) of the FAA Reauthorization Act of 2018, which requires the FAA to consider any events or circumstances that may necessitate renewal before the registration expiration.

The Registry has previously encountered instances where the FAA has determined that Certificates of Aircraft Registration contain inaccurate information. However, because part 47 does not currently contain a provision allowing the FAA to require a new registration or early renewal, the FAA has had difficulty correcting the inaccurate information. Due to the extension in duration of registration certificate, the FAA also anticipates that registration information may need to be updated more frequently, as supported by Congress's inclusion of the requirement in section 556(b). This amendment enables timely provision of accurate aircraft registration information.

C. Other Part 47 Amendments

The FAA is making several other amendments to 14 CFR part 47. First, the FAA is revising 14 CFR 47.31(c)(1) by removing the time limit within which the FAA must either issue a letter extending the temporary authority to continue to operate or deny the application. Section 47.31(c)(2) provides a 12-month overall limit on such temporary authority. Therefore, the FAA finds the requirement to issue this separate letter unnecessary and is removing this requirement.

Second, the FAA is removing references to the Re-Registration program, which expired on January 1, 2014. This will include removing § 47.40(a) and revising § 47.17(a)(7) to delete the word “re-registration.” The Re-Registration Rule was intended to clean up aircraft records and issue certificates with a three-year expiration date. Registered owners desiring to continue registration were required to re-register their aircraft within the established schedule. The Re-Registration process ended December 31, 2013.

Third, the FAA also makes corresponding and technical revisions to § 47.61(c).

V. Regulatory Notices and Analyses

Federal agencies consider impacts of regulatory actions under a variety of executive orders and other requirements. First, Executive Order 12866 and Executive Order 13563 direct that each Federal agency shall propose or adopt a regulation only upon a reasoned determination that the benefits of the intended regulation justify its costs. Second, the Regulatory Flexibility Act of 1980 (Pub. L. 96–354) requires agencies to analyze the economic impact of regulatory changes on small entities. Third, the Trade Agreements Act (Pub. L. 96–39) prohibits agencies from setting standards that create unnecessary obstacles to the foreign commerce of the United States. In developing U.S. standards, the Trade Act requires agencies to consider international standards and, where appropriate, that they be the basis of U.S. standards. Fourth, the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4) requires agencies to prepare a written assessment of the costs, benefits, and other effects of proposed or final rules that include a Federal mandate likely to result in the expenditure by State, local, or tribal governments, in the aggregate, or by the private sector, of \$100 million or more annually (adjusted for inflation with base year of 1995). This portion of the preamble provides

the FAA's regulatory evaluation of the economic impacts of this NPRM.

In conducting these analyses, the FAA has determined that this rule: (1) would result in net cost savings; (2) will impose no new costs to aircraft owners and the public without any reduction to airline safety; (3) is not an economically “significant regulatory action” under section 3(f) of Executive Order 12866; (4) will not have a substantial economic impact on a significant number of small entities; (5) will not create unnecessary obstacles to the foreign commerce of the United States; and (6) will not impose an unfunded mandate on State, local, or tribal governments, or on the private sector by exceeding the threshold identified above.

A. Regulatory Evaluation

1. Need for Regulatory Action

Section 556 of the FAA Reauthorization Act of 2018 directed the FAA to increase the duration of a certificate for noncommercial general aviation aircraft from three years to seven years. However, the FAA promulgates this rulemaking to modify the duration of a certificate for all registered aircraft, including commercial aircraft, instead of only noncommercial general aviation aircraft. Distinguishing commercial aircraft from noncommercial aircraft within the Registry is impractical and, therefore, not cost-justified. Additionally, the FAA did not identify quantifiable or monetized benefits of not extending the duration of certificates of commercial aircraft.

While the rule will reduce revenues to the FAA, it will provide private benefits in terms of cost savings to commercial and noncommercial general aviation aircraft owners.

2. Regulatory Alternatives

The FAA considered the following regulatory alternative for this rulemaking:

Extend the Duration of a Certificate to 7 Years for Only Noncommercial Aircraft

The FAA was directed to provide relief to noncommercial general aviation aircraft owners by extending the current three-year duration of a certificate to a seven-year duration. However, after reviewing all the potential costs to multiple FAA programs in identifying the commercial aircraft within the Registry and separating them from noncommercial general aviation aircraft, the FAA did not find the congressionally mandated alternative as cost beneficial as there are no

quantifiable or monetized benefits of not extending the duration of certificates of commercial aircraft.

3. Baseline Conditions

The Registry collects the information necessary to establish and maintain the record for all United States civil aircraft. The aircraft record consists of three distinct elements: information about the registered owner of the aircraft, information about recorded aircraft security interests, and information concerning the airworthiness of the aircraft. In addition to the aircraft record, the Registry maintains certain ancillary files that contain related information maintained in support of registration and recordation.

The aircraft registration application requires information on the aircraft, including the registration number, manufacturer and model, and serial number. The aircraft record collected by the application does contain certain elements of personally identifiable information (PII), although generally, the PII collected is not sensitive in nature. PII collected includes registered owner name(s), aircraft identifiers, mailing address, email address,¹² and telephone numbers. The Registry does not ask the registered owners the nature or purpose of the aircraft operations, such as whether the aircraft will be used for commercial operations, noncommercial operations (e.g., recreational or hobby), or a combination of both.

After a six-year rulemaking effort, the Re-Registration and Renewal program was implemented on October 1, 2010. The goal of the program was to develop a process that would achieve a level of registration data reliability to meet the current and evolving needs of users of the Registry. With the implementation of 14 CFR 47.40, aircraft owners who intended to maintain their registration were required to re-register their aircraft by December 31, 2013. Beginning October 1, 2010, all certificates issued expire 3 years from the date of issuance, but were renewable for successive three-year terms if there was no change in the ownership status of the aircraft.

Since re-registration ended on December 31, 2013, two three-year renewal cycles have taken place. The most current Aircraft Registration Information Collection Request (ICR 2120–0042), which expires on March 31, 2024, provides details of Registry records, including the annual numbers for “Applications” (74,443), “Renewal Form (paper)” (20,053), and “Renewal

Form (electronic)” (55,919), along with forms that provide evidence of ownership, security agreement and flight hours report, such as AC Forms 8050–2, 8050–4, 8050–88, 8050–88A, 8050–98, and 8050–117.

The supporting statement for ICR 2120–0042 shows 75,972 renewals annually, including 55,919 electronic renewals and 20,053 paper renewals, based on workload statistics from FY 2019.¹³ A total of 235,304 aircraft had their registration renewed during the last three fiscal years, including 75,972 in FY 2019, 83,711 in FY 2020, and 75,621 in FY 2021. Based on these three fiscal years’ registration figures, the FAA estimates approximately 78,435 (=235,304/3) aircraft registration renewals each year. This estimate includes all aircraft, commercial and noncommercial.

4. Key Assumptions, Data Sources and Uncertainties

The FAA used the following assumptions and data sources:

a. Aircraft Registry, ICR 2120–0042, FAA Forecast of General Aviation Aircraft (2021–2041)

The FAA based its analysis of the rule primarily on data stored in the Aircraft Registration Database (‘Registry Database’) and ICR 2120–0042.¹⁴

b. Period of Analysis

The FAA used a 21-year period of analysis, or three seven-year renewal cycles, to show the full impacts of the rule starting from the effective date of this rule.¹⁵

c. Affected Aircraft

As discussed and explained in the Baseline Conditions above, the FAA estimated that approximately 78,435 aircraft registrations would be renewed each year using the FY 2019 through FY 2021 statistics on renewals using both electronic and paper versions of the Renewal Forms.

¹³ https://www.reginfo.gov/public/do/PRAViewDocument?ref_nbr=202005-2120-001.

¹⁴ General information about FAA’s Aircraft Registry can be found here: http://www.faa.gov/licenses_certificates/aircraft_certification/aircraft_registry/.

Information Collection 2120–0042 documentation is last accessed February 4, 2020 on the following web page of Office of Information and Regulatory Affairs (OIRA) at the Office of Management and Budget (OMB): <https://www.reginfo.gov/public/do/PRAOMBHistory?ombControlNumber=2120-0042>.

¹⁵ 21-year period of analysis should not be construed as if it will take the entire period of 21 years for the rule to take effect on affected aircraft and their owners. The rule will take effect as of the date shown above in the preamble and will immediately extend the 3-year length of existing aircraft registrations to 7-year.

The FAA Aerospace Forecasts provide detailed forecast for the next twenty years (2021–2041) for all classes of aircraft. General Aviation aircraft make up the majority of aircraft that will be affected by the rule. For 2020, the FAA estimated there are 204,980 General Aviation aircraft, a total that is forecasted to increase slightly to 208,790 at the end of the forecast period in 2041.¹⁶ Other categories of aircraft that need to register with the Aircraft Registry are passenger jets, cargo jets, and regional carriers. When all these aircraft are included, the FAA estimated 211,248 aircraft (General Aviation, Passenger Jets, Cargo Jets and Regional Carriers, all combined) for 2020. The FAA forecasted a total of 211,606 aircraft for this group of aircraft. The forecast figure is virtually unchanged from the current inventory of aircraft. Therefore, we assumed that the growth rate for the Aircraft Registry throughout the 21-year period of analysis would be zero, meaning the total number of aircraft in the Aircraft Registry would be unchanged.¹⁷

d. Uncertainties

The 2010 registry database showed a total number of 360,055 registered aircraft. As of December 31, 2020, the total number of registered aircraft was 286,989, a decrease of 73,066 aircraft that were de-registered in ten years, which included three 3-year renewal cycles. This significant drop of 20 percent is mainly attributed to the Re-Registration Rule that began in October 2010.¹⁸

The total number of aircraft captured in the Aircraft Registry may continue to decline based on the current trends the FAA has observed. However, the FAA cannot determine or predict with any certainty how many aircraft will be de-registered in the coming renewal cycles. Therefore, we used the average of registration data from the last three fiscal years (FY 19 through FY 21) for the current total inventory of registered aircraft: 235,304.

¹⁶ Appendix C: Forecast Tables provide the details of each class of aircraft including General Aviation, Passenger Jets, Cargo Jets and Regional Carriers https://www.faa.gov/data_research/aviation/aerospace_forecasts/media/Appendix_C_Forecast_Tables.pdf.

¹⁷ The FAA recognizes the potential of proposed unmanned air taxis and delivery drones that would need to be registered with the FAA’s Registry. However, the number of these unmanned aircraft cannot be forecasted and included in this regulatory analysis.

¹⁸ The Re-Registration Rule gave the FAA the ability to remove aircraft from the FAA’s registry database that no longer met registry requirements.

¹² Email addresses will be collected on the next revision to the Application and Renewal Forms.

5. Cost Savings

The FAA is changing the duration of an aircraft registration certificate from the current three-year cycle to a seven-year cycle. This change would result in cost savings to aircraft owners. The FAA did not identify or assess any other impacts for this rule.

Using the baseline total number of 235,304 aircraft that renewed their registration over the last three-year cycle, the FAA calculated an annual average of 78,435 aircraft owners to renew their aircraft's registration by using either electronic or paper Renewal Form.¹⁹

The supporting statement for ICR 2120–0042 from March 26, 2021, estimated 30 minutes (0.5 hours) to fill out the Renewal Form (either electronic or paper).

The FAA calculates an average of 39,217.5 annual burden hours (.5 hours × 78,435 renewals) for aircraft owners or their representatives to renew their aircraft registrations. Using a \$25 per hour wage for a title search clerk/legal assistant, as published in the latest ICR 2120–0042 Supporting Statement, the FAA estimates the baseline current annual burden for aircraft owners would be \$1,372,613 [(\$5 application fee + \$12.5 labor cost²⁰) × 78,435 renewals], with \$980,433 representing baseline opportunity costs associated with registration time and \$392,175 representing baseline fees collected, which are considered baseline transfer payments from the private sector to government.

With this rule changing the duration of each certificate to seven years and the current inventory of aircraft in the Registry remaining the same at 235,304 throughout the 21-year period of analysis, the FAA estimates the average annual renewal applications to decrease to 33,615 (=235,304/7). Using the same assumptions for application fee and wage rate, the annual burden for aircraft owners would be \$588,262 [(\$5 application fee + \$12.5 labor cost) × 33,615], with \$420,187 representing the

new opportunity cost associated with registration and \$168,075 representing the new fees (or transfers) paid under this rule. This will result in annual private cost savings of \$784,344 (undiscounted) to the aircraft owners.

The social cost savings attributable to this rule would be the difference in opportunity cost associated with time spent on registration. Note that the differences in total registration fees paid and collected are considered transfers with no net change in social costs or benefits. Based on the calculations as discussed earlier, the annual undiscounted cost savings of this rule would be equal to \$560,246 (\$980,433–\$420,188). Over a 21-year period of analysis, the FAA estimates that the total undiscounted cost savings of this rule would be \$11,765,162. At 7 percent and 3 percent discount rates, the net present value of those cost savings would be \$6,070,559 and \$8,636,203, respectively. Annualized cost savings would be \$523,594 and \$543,928 at 7 percent and 3 percent discount rates, respectively.

6. Costs

The FAA did not identify any incremental costs or burden to the 235,304 aircraft owners that would be affected by this rule. The FAA determined that there would be neither a reduction in public safety nor an increase in costs to the public.

7. Distributional Effects

As discussed previously, with the increase in the duration of aircraft registration from 3 to 7 years, there would be a decrease in registration fees paid by aircraft owners, which would reduce FAA's revenues. Over a 21-year period, this amount is \$4,706,065 (undiscounted), and its net present value is \$209,438 and \$217,571 (at 7 percent and 3 percent discount rates, respectively).

B. Regulatory Flexibility Determination

The Regulatory Flexibility Act of 1980 (Pub. L. 96–354) (RFA) establishes “as a principle of regulatory issuance that agencies shall endeavor, consistent with the objectives of the rule and of applicable statutes, to fit regulatory and informational requirements to the scale of the businesses, organizations, and governmental jurisdictions subject to regulation.” To achieve this principle, agencies are required to solicit and consider flexible regulatory proposals and to explain the rationale for their actions to assure that such proposals are given serious consideration. The RFA covers a wide range of small entities, including small businesses, not-for-

profit organizations, and small governmental jurisdictions.

Agencies must perform a review to determine whether a rule will have a significant economic impact on a substantial number of small entities. If the agency determines that it will, the agency must prepare a regulatory flexibility analysis as described in the RFA. However, if an agency determines that a rule is not expected to have a significant economic impact on a substantial number of small entities, section 605(b) of the RFA provides that the head of the agency may so certify and a regulatory flexibility analysis is not required. The certification must include a statement providing the factual basis for this determination.

The FAA expects the economic impact of this rule on a small entity will be small. The rule will provide relief to small entity aircraft owners in terms of a small reduction in labor costs and registration fees per aircraft due to a longer duration for the certificate they hold for their aircraft from the current 3-year to the 7-year expiration of an aircraft registration certificate. Therefore, the FAA has determined this rule will not impose a significant economic impact on a substantial number of small entities.

C. International Trade Impact Assessment

The Trade Agreements Act of 1979 (Pub. L. 96–39), as amended by the Uruguay Round Agreements Act (Pub. L. 103–465), prohibits Federal agencies from establishing standards or engaging in related activities that create unnecessary obstacles to the foreign commerce of the United States. Pursuant to these Acts, the establishment of standards is not considered an unnecessary obstacle to the foreign commerce of the United States, so long as the standard has a legitimate domestic objective, such as the protection of safety, and does not operate in a manner that excludes imports that meet this objective. The statute also requires consideration of international standards and, where appropriate, that they be the basis for U.S. standards.

The FAA has assessed the potential effect of this rule and determined that it ensures the safety of the American public and does not exclude imports that meet this objective. As a result, this rule is not considered as creating an unnecessary obstacle to foreign commerce.

D. Unfunded Mandates Assessment

Title II of the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4)

¹⁹ The FAA recognizes that with the current registration and renewal cycle being three years, the bulk of renewals will occur during the first three years of the first seven-year cycle. Renewals in years 4 through 7 are likely to be significantly less for a few cycles. Renewals for years 4 through 7 will result from registering expired aircraft, registering new aircraft, and changes in ownership that result in a new registration. However, for the sake of simplicity of our cost estimation, we assumed that average annual renewals to stabilize around that annual average figure (78,435) in the second and third seven-year renewal cycles, albeit this assumed annual average is likely to be reached in the third seven-year cycle.

²⁰ \$25 per hour wage rate multiplied by 30 minutes, or 0.5 hour, is \$12.50 as labor cost of renewing an aircraft registration.

requires each Federal agency to prepare a written statement assessing the effects of any Federal mandate in a proposed or final agency rule that may result in an expenditure of \$100 million or more (in 1995 dollars) in any one year by State, local, and tribal governments, in the aggregate, or by the private sector; such a mandate is deemed to be a "significant regulatory action." The FAA currently uses an inflation-adjusted value of \$164 million in lieu of \$100 million. This rule does not contain such a mandate; therefore, the requirements of Title II of the Act do not apply.

E. Paperwork Reduction Act

The Paperwork Reduction Act of 1995 (44 U.S.C. 3507(d)) requires that the FAA consider the impact of paperwork and other information collection burdens imposed on the public. According to the 1995 amendments to the Paperwork Reduction Act (5 CFR 1320.8(b)(2)(vi)), an agency may not collect or sponsor the collection of information, nor may it impose an information collection requirement unless it displays a currently valid Office of Management and Budget (OMB) control number.

OMB Control Number 2120-0042 is revised to reflect the reduced number of respondents, annual burden hours, and monetized costs and has been submitted to OMB for review.

Summary: The FAA amends 14 CFR part 47, § 47.40, requiring aircraft registration be renewed seven years after the issuance of the certificate and every seven years thereafter, as long as ownership is not transferred or the registration has been canceled. Information from the Renewal Form is used to update registration information in the Registry's database.

Use: This information collection supports the Department of Transportation's strategic goals on safety and security. The information collected is necessary to obtain a certificate.

49 U.S.C. 44101(a) provides that a person may operate an aircraft only when it is registered under section 44013.

Prior to adoption of this direct final rule, the certificate has a 3-year expiration date. If registration is to continue, each aircraft owner must apply for renewal by completing and submitting a Renewal Form with appropriate fee prior to the expiration date on the certificate. The owner verifies the existing registration information and reports any changes. The Registry uses this information to update aircraft ownership information and places the form in the record. This rule reduces the current requirement for

renewal from once every three years to once every seven years. This rule reduces the information collected to support the Registry's database.

Respondents: The likely respondents to this information requirement are aircraft owners who want to continue registration past the expiration date on their certificate. The FAA estimates the number of registration renewals would be 33,615 annually; however, the number of aircraft owners affected may vary depending upon the type of registration (e.g., individual, partnership, co-ownership, etc.). Currently, the average number of renewals is estimated at 78,435 (dividing by 3, the frequency of years in which aircraft owners are required to renew registration the total number of renewals, 235,304 (75,972 + 83,711 + 75,621) using FY19, FY20 and FY21 data.

Frequency: The FAA estimates that there would be 33,615 registration renewal forms completed annually over the 21-year period of analysis used for this rule. This is based on the current estimate of 235,304 active registered aircraft, calculated using the total number of registered aircraft from FY 2019 through FY 2021.

Annual Burden Estimate: Over 21 years, the FAA estimates an average of 33,615 Renewal Forms (either electronic or paper) would need to be completed each year. The time to complete the Renewal Form is estimated at 30 minutes. Therefore, 16,808 hours would be spent annually completing the required form. Currently, the FAA estimates an average of 39,217 annual burden hours. As described in the preliminary Regulatory Evaluation, the FAA estimates the hourly rate of an aircraft owner's or its representative's (title search or legal clerk) time at \$25 per hour in 2020 dollars. The current average annual cost of completing 78,435 renewal forms, spending 39,217 hours, is approximately \$980,433. On the other hand, the average cost per year to aircraft owners of renewing registration every 7 years would be \$420,200 (16,808 hours multiplied by \$25/hour). In addition, aircraft owners would pay a total of \$168,075 to the FAA to register their aircraft (\$5 fee multiplied by 33,615). The total annual burden to aircraft owners, including time to fill out the Renewal Form and \$5 registration fee, would be \$588,275.

The agency is soliciting comments to—

(1) Evaluate whether the proposed information requirement is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;

(2) Evaluate the accuracy of the agency's estimate of the burden;

(3) Enhance the quality, utility, and clarity of the information to be collected; and

(4) Minimize the burden of collecting information on those who are to respond, including by using appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology.

Individuals and organizations may send comments on the information collection requirement to the address listed in the **ADDRESSES** section at the beginning of this preamble by December 22, 2022. Comments also should be submitted to the Office of Management and Budget, Office of Information and Regulatory Affairs, Attention: Desk Officer for FAA, New Executive Office Building, Room 10202, 725 17th Street NW, Washington, DC 20053.

F. International Compatibility

In keeping with U.S. obligations under the Convention on International Civil Aviation, it is FAA policy to conform to International Civil Aviation Organization (ICAO) Standards and Recommended Practices to the maximum extent practicable. The FAA has reviewed the corresponding ICAO Standards and Recommended Practices and has identified no differences with this rule.

Further, ICAO Standards set forth a model registration certificate. The FAA's certificate will exceed the standard in that model because the certificate will still include an expiration date.

G. Environmental Analysis

FAA Order 1050.1F identifies FAA actions that are categorically excluded from preparation of an environmental assessment or environmental impact statement under the National Environmental Policy Act in the absence of extraordinary circumstances. The FAA has determined this rulemaking action qualifies for the categorical exclusion identified in paragraph 5–6.6 for regulations and involves no extraordinary circumstances.

VI. Executive Order Determinations

A. Executive Order 13132, Federalism

The FAA has analyzed this rule under the principles and criteria of Executive Order 13132, Federalism. The FAA has determined that this action would not have a substantial direct effect on the

States, or the relationship between the Federal Government and the States, or on the distribution of power and responsibilities among the various levels of government, and, therefore, will not have federalism implications.

B. Executive Order 13211, Regulations That Significantly Affect Energy Supply, Distribution, or Use

The FAA analyzed this rule under Executive Order 13211, Actions Concerning Regulations that Significantly Affect Energy Supply, Distribution, or Use. The agency has determined that it will not be a “significant energy action” under the executive order and will not be likely to have a significant adverse effect on the supply, distribution, or use of energy.

C. Executive Order 13609, International Cooperation

Executive Order 13609, Promoting International Regulatory Cooperation, promotes international regulatory cooperation to meet shared challenges involving health, safety, labor, security, environmental, and other issues and to reduce, eliminate, or prevent unnecessary differences in regulatory requirements. The FAA has analyzed this action under the policies and agency responsibilities of Executive Order 13609, and has determined that this action will have no effect on international regulatory cooperation.

VII. Additional Information

A. Comments Invited

The FAA invites interested persons to participate in this rulemaking by submitting written comments, data, or views. The most helpful comments reference a specific portion of the rule, explain the reason for any recommended change, and include supporting data. To ensure the docket does not contain duplicate comments, commenters should send only one copy of written comments, or if comments are filed electronically, commenters should submit only one time.

The FAA will file in the docket all comments it receives, as well as a report summarizing each substantive public contact with FAA personnel concerning this rulemaking. Before acting on this rulemaking, the FAA will consider all comments it receives on or before the closing date for comments. The agency may change this rule in light of the comments it receives.

B. Confidential Business Information

Confidential Business Information (CBI) is commercial or financial information that is both customarily and actually treated as private by its owner.

Under the Freedom of Information Act (FOIA) (5 U.S.C. 552), CBI is exempt from public disclosure. If your comments responsive to this direct final rule contain commercial or financial information that is customarily treated as private, that you actually treat as private, and that is relevant or responsive to this direct final rule, it is important that you clearly designate the submitted comments as CBI. Please mark each page of your submission containing CBI as “PROPIN.” The FAA will treat such marked submissions as confidential under the FOIA, and they will not be placed in the public docket of this direct final rule. Submissions containing CBI should be sent to the person in the **FOR FURTHER INFORMATION CONTACT** section of this document. Any commentary that the FAA receives which is not specifically designated as CBI will be placed in the public docket for this rulemaking.

C. Electronic Access and Filing

A copy of this direct final rule, all comments received, any confirmation document, and all background material may be viewed online at <https://www.regulations.gov> using the docket number listed above. A copy of this direct final rule will be placed in the docket. Electronic retrieval help and guidelines are available on the website. It is available 24 hours each day, 365 days each year. An electronic copy of this document may also be downloaded from the Office of the Federal Register’s website at <https://www.federalregister.gov> and the Government Publishing Office’s website at <https://www.govinfo.gov>. A copy may also be found on the FAA’s Regulations and Policies website at https://www.faa.gov/regulations_policies.

Copies may also be obtained by sending a request to the Federal Aviation Administration, Office of Rulemaking, ARM-1, 800 Independence Avenue SW, Washington, DC 20591, or by calling (202) 267-9677. Interested persons must identify the docket or amendment number of this rulemaking.

All documents the FAA considered in developing this rule, including economic analyses and technical reports, may be accessed in the electronic docket for this rulemaking.

D. Small Business Regulatory Enforcement Fairness Act

The Small Business Regulatory Enforcement Fairness Act (SBREFA) of 1996 requires the FAA to comply with small entity requests for information or advice about compliance with statutes and regulations within its jurisdiction. A small entity with questions regarding

this document may contact its local FAA official, or the person listed under the **FOR FURTHER INFORMATION CONTACT** heading at the beginning of the preamble. To find out more about SBREFA on the internet, visit https://www.faa.gov/regulations_policies/rulemaking/sbre_act/.

List of Subjects in 14 CFR Part 47

Aircraft, Reporting, and recordkeeping requirements.

The Amendment

In consideration of the foregoing, the FAA amends chapter I of title 14, Code of Federal Regulations, as follows:

PART 47—AIRCRAFT REGISTRATION

■ 1. The authority citation for part 47 is revised to read as follows:

Authority: 4 U.S.T. 1830; Pub. L. 115–254, Pub. L. 108–297, 118 Stat. 1095 (49 U.S.C. 40101 note, 49 U.S.C. 44101 note); 49 U.S.C. 106(f), 106(g), 40113–40114, 44101–44108, 44110–44113, 44703–44704, 44713, 45302, 46104, 46301.

§ 47.15 [Amended]

■ 2. Amend § 47.15 by removing paragraph (i)(1) and redesignating paragraphs (i)(2) through (i)(4) as paragraphs (i)(1) through (i)(3).

■ 3. Amend § 47.17 by revising paragraph (a) to read as follows.

§ 47.17 Fees.

(a) The fees for applications under this part are as follows:

(1) Certificate of Aircraft Registration (each aircraft)	\$5.00
(2) Dealer’s Aircraft Registration Certificate	10.00
(3) Additional Dealer’s Aircraft Registration Certificate (issued to same dealer)	2.00
(4) Special registration number (each number)	10.00
(5) To change, reassign, or reserve a registration number	10.00
(6) Replacement Certificate of Aircraft Registration	2.00
(7) Renewal Certificate of Aircraft Registration	5.00

* * * * *

■ 4. Amend § 47.31 by revising paragraph (c)(1) to read as follows:

§ 47.31 Application.

* * * * *

(c) * * *

(1) This temporary authority is valid for operation within the United States until the date the applicant receives the Certificate of Aircraft Registration or until the date, the FAA denies the

application, or as provided by paragraph (c)(2) of this section.

* * * * *

■ 5. Revise § 47.40 to read as follows:

§ 47.40 Registration expiration and renewal.

(a) *Initial Registration.* A Certificate of Aircraft Registration issued in accordance with § 47.31 expires seven years after the last day of the month in which it is issued.

(b) *Renewal.* Each holder of a Certificate of Aircraft Registration, AC Form 8050–3, containing an expiration date may apply for renewal of a Certificate of Aircraft Registration by submitting an Aircraft Registration Renewal Application, AC Form 8050–1B, and the fee required by § 47.17 during the six months preceding the expiration date for the Certificate of Aircraft Registration.

(1) A Certificate of Aircraft Registration issued under this paragraph after January 23, 2023 expires seven years after the last day of the month in which it was issued.

(2) A Certificate of Aircraft Registration that is in effect on January 23, 2023 expires seven years after the last day of the month in which it is issued, notwithstanding the expiration date on the valid Certificate of Aircraft Registration.

(c) *Inaccurate Information.* The Administrator may require the owner of a registered aircraft to submit a complete Aircraft Registration Application, AC Form 8050–1, and fee prior to the expiration date if the Administrator finds that the Certificate of Aircraft Registration contains inaccurate information.

■ 6. Amend § 47.61 by revising paragraph (c) to read as follows:

§ 47.61 Dealer's Aircraft Registration Certificates.

* * * * *

(c) If a Dealer's Aircraft Registration Certificate for an aircraft registered under this subpart expires in accordance with § 47.71, the aircraft owner must submit an application for aircraft registration in accordance with § 47.31 or the assignment of registration number will be canceled in accordance with § 47.15(i)(2).

Issued under authority provided by 49 U.S.C. 106(f), 44701(a), and 44703 in Washington, DC, on or about November 16, 2022.

Billy Nolen,

Acting Administrator.

[FR Doc. 2022–25289 Filed 11–21–22; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Parts 61 and 68

[Docket No. FAA–2021–1040; Amdt. Nos. 61–152 and 68–2]

RIN 2120–AL51

Medical Certification Standards for Commercial Balloon Operations

AGENCY: Federal Aviation Administration (FAA), Department of Transportation (DOT).

ACTION: Final rule.

SUMMARY: The FAA is amending its regulations to require airmen hold a valid second-class medical certificate when exercising the privileges of a commercial pilot certificate in a balloon for compensation or hire except when conducting flight training in a balloon. In addition, the FAA makes miscellaneous amendments related to medical certification requirements for special medical flight tests and a minor change to the BasicMed regulations.

DATES: This rule is effective December 22, 2022, except for the amendments to §§ 61.3(c)(2)(vi), 61.23(a)(2)(i), 61.23(a)(2)(ii), 61.23(a)(2)(iii), 61.23(b)(3), 61.23(b)(4), 61.23(b)(5), 61.23(d)(1)(iii), and 61.23(d)(2)(i), which are effective May 22, 2023.

ADDRESSES: For information on where to obtain copies of rulemaking documents and other information related to this final rule, see “How to Obtain Additional Information” in the **SUPPLEMENTARY INFORMATION** section of this document.

FOR FURTHER INFORMATION CONTACT:

Bradley Zeigler, Training & Certification Group, Federal Aviation Administration, 800 Independence Avenue SW, Washington, DC 20591; telephone (202) 267–9601; email Bradley.C.Zeigler@faa.gov.

SUPPLEMENTARY INFORMATION:

List of Abbreviations and Acronyms Frequently Used in This Document

AMCD Aerospace Medical Certification Division
ADHD Attention Deficit Hyperactivity Disorder
AME Aviation Medical Examiner
ASI Aviation Safety Inspector
ATP Airline Transport Pilot
BFA Balloon Federation of America
IRFA Initial Regulatory Flexibility Analysis
LOA Letter of Authorization
NAS National Airspace System
NDR National Driver Register
NPRM Notice of proposed rulemaking
NTSB National Transportation Safety Board
PDPS Problem Driver Pointer System

PIC Pilot in Command
SIC Second in Command
SODA Statement of Demonstrated Ability

Table of Contents

I. Executive Summary	
A. Purpose of the Regulatory Action	
B. Changes Made in This Final Rule	
C. Summary of the Costs and Benefits	
II. Authority for This Rulemaking	
III. Background	
A. Need for Regulation	
B. National Transportation Safety Board (NTSB) Recommendations	
C. Summary of the NPRM	
D. General Overview of Comments	
IV. Discussion of Comments and the Final Rule	
A. Application of Medical Certificate Requirement to Only Operations Based on Size of Envelope or Passenger Capacity	
B. Application of Rule to Commercial Balloon Operations Without Passengers	
C. Drug and Alcohol Testing	
D. Miscellaneous Issues	
E. Comments Regarding Miscellaneous Amendments	
V. Regulatory Notices and Analyses	
A. Summary of the Regulatory Impact Analysis	
B. Regulatory Flexibility Act	
C. International Trade Impact Assessment	
D. Unfunded Mandates Assessment	
E. Paperwork Reduction Act	
F. International Compatibility	
G. Environmental Analysis	
VI. Executive Order Determination	
A. Executive Order 13132, Federalism	
B. Executive Order 13211, Regulations That Significantly Affect Energy Supply, Distribution, or Use	
C. Executive Order 13609, International Cooperation	
VII. Privacy	
VIII. Additional Information	
A. Electronic Access and Filing	
B. Small Business Regulatory Enforcement Fairness Act	

I. Executive Summary

A. Purpose of the Regulatory Action

This final rule implements section 318 (“Commercial Balloon Pilot Safety Act of 2018”) of Public Law 115–254, the FAA Reauthorization Act of 2018. In addition, this final rule responds to National Transportation Safety Board (NTSB) Safety Recommendation A–17–034, which recommends that the FAA remove the medical certification exemption in part 61 for commercial balloon pilots¹ receiving compensation for transporting passengers.

This final rule amends §§ 61.3 and 61.23 of title 14 of the Code of Federal Regulations (14 CFR) to require commercial balloon pilots conducting

¹ The FAA uses the term “commercial balloon pilots” in this rule to refer to airmen conducting operations in a balloon for compensation or hire, including operations involving the carriage of persons or property.

operations for compensation or hire to hold a valid second-class medical certificate. However, this final rule will continue to allow pilots to provide flight training in balloons without requiring a medical certificate. The rule also amends the table setting forth medical certificate durations in § 61.23(d) for consistency with amendments to §§ 61.3 and 61.23(a) and (b).

The FAA is also making two miscellaneous amendments. First, the FAA is amending sections of part 61 to allow persons to act as pilot in command (PIC) during a special medical flight test authorized under part 67 without holding a medical certificate.

The second is making a minor change to regulations amended or established by the Alternative Pilot Physical Examination and Education Requirements final rule to² allow a required pilot flightcrew member who is not acting as PIC to operate under BasicMed.

B. Changes Made in This Final Rule

The FAA published a Notice of Proposed Rulemaking (NPRM), Medical Certification Standards for Commercial Balloon Operations on November 18, 2021 (86 FR 64419). This rulemaking finalizes the proposal, without change.

C. Summary of the Costs and Benefits

This final rule will generate costs for balloon pilots to obtain a second-class medical certificate and for some pilots to seek an Authorization for Special Issuance of a Medical Certificate (special issuance). There will also be costs to the FAA to implement this requirement in terms of reviewing and processing submissions related to certification. The FAA estimates the present value of total costs over ten years is \$2.4 million to \$16.3 million with a mid-estimate of \$6.9 million at a 7 percent discount rate and \$2.9 million to \$19.9 million with a mid-estimate of \$8.4 million at a 3 percent discount rate. The annualized costs over ten years are \$0.3 million to \$2.3 million with a mid-estimate of \$1.0 million at a 7 percent discount rate and \$0.3 million to \$2.3 million with a mid-estimate of \$1.0 million at a 3 percent discount rate. The wide range in the cost estimates primarily reflects the uncertainty on the

number of commercial balloon pilots who will seek medical certification.

The benefits of the final rule include enhanced safety of commercial balloon operations through reduced risks of accidents, fatalities, and injuries caused by medical impairment of balloon pilots.

II. Authority for This Rulemaking

The FAA's authority to issue rules on aviation safety is in Title 49 of the United States Code. Section 106 describes the authority of the FAA Administrator. Subtitle VII, Aviation Programs, describes in more detail the scope of the Agency's authority.

The FAA is issuing this final rule under the authority described in Section 44701, General Requirements; Section 44702, Issuance of Certificates; and Section 44703, Airman Certificates. Under these sections, the FAA prescribes regulations and minimum standards for practices, methods, and procedures the Administrator finds necessary for safety in air commerce. The FAA is also authorized to issue certificates, including airman certificates and medical certificates, to qualified individuals. This rulemaking is within the scope of that authority.

Further, Section 318 of Public Law 115–254 directs the Administrator to “revise 14 CFR 61.3(c) (relating to second-class medical certificates) to apply to an operator of an air balloon to the same extent such regulations apply to a pilot flightcrew member of other aircraft.”

III. Background

A. Need for Regulation

On the morning of July 30, 2016, a hot air balloon struck power lines and burst into flames over a pasture near Lockhart, Texas, killing all 15 passengers and the pilot. The flight was conducted in a balloon (N2469L) operated by Heart of Texas Hot Air Balloon Rides under part 91 as a sightseeing passenger flight. The pilot was exercising the privileges of a commercial pilot certificate.

Through its investigation, the NTSB determined that the pilot had been diagnosed with depression and attention deficit hyperactivity disorder (ADHD)³ and identified medications found in the pilot's system that are known to cause impairment.⁴

The NTSB determined that the probable cause of this accident was the pilot's pattern of poor decision-making that led to the initial launch, continued flight in fog and above clouds, and descent near or through clouds that decreased the pilot's ability to see and avoid obstacles. The NTSB further determined that (1) the pilot's impairing medical conditions and medications, and (2) the FAA's policy to not require a medical certificate for commercial balloon pilots, were contributing factors in the accident.⁵

Prior to the Heart of Texas accident, the FAA generally considered commercial balloon operations to be a low-risk and extremely small segment of aviation in the United States. Research conducted by the FAA revealed 54 commercial hot air balloon accidents between 2003 and 2013, including four fatal accidents. In 2015, commercial sightseeing balloon operations represented 0.057% of the flight hours of total civil aircraft operations.⁶ Prior to this accident, pilots conducted commercial balloon operations in the U.S. for decades without any accidents specifically attributed to medical deficiencies.

In response to the Heart of Texas accident, the FAA worked with industry advocacy organization Balloon Federation of America (BFA) to support its 2017 Envelope of Safety Program.⁷ The voluntary program promoted safety within the commercial balloon industry by educating consumers with information when making balloon ride purchase decisions and offered multiple tiers of safety accreditation by the BFA. While the FAA supports the efforts of the BFA to enhance safety and professionalism of the industry while providing consumers with more information when choosing a commercial balloon ride operator, the agency notes that not all balloon operators are members of the BFA, and BFA members are not required to adhere to any specific standards in order to maintain professional membership. Consequently, the FAA considered BFA's efforts to achieve voluntary compliance with industry standards to be insufficient alone to address the need for additional oversight of airmen

² The Alternative Pilot Physical Examination and Education Requirements final rule amended sections of part 61 and established part 68 to allow persons to conduct certain flight operations in powered aircraft while exercising the privileges of a private pilot certificate without holding a medical certificate issued under part 67. The provisions established by Alternative Pilot Physical Examination and Education Requirements final rule will be collectively referred to in this preamble as BasicMed. 82 FR 3149 (Jan. 11, 2017).

³ ADHD is known to cause cognitive deficits that may affect decision-making and, ultimately, safety of flight.

⁴ The medications identified by the NTSB are listed on the FAA's “Do Not Issue” and “Do Not Fly” lists found in the AME Guide. https://www.faa.gov/about/office_org/headquarters_offices/avs/offices/aam/ame/guide/pharm/dni_dnf/.

⁵ NTSB Accident Report NTSB/AAR–17/03 PB2018–100161 at p. 49.

⁶ FAA Docket Submission to the National Transportation Safety Board for the investigation of the Heart of Texas Hot Air Balloon Accident Balony Kubicek BB85Z balloon, N2469L, Lockhart, Texas; July 30, 2016, Dated April 19, 2017. Page 6.

⁷ <https://www.bfa.net/88888979-news/1579-envelope-of-safety-program-announced>.

conducting balloon operations for compensation or hire.

In Section 318 (“Commercial Balloon Pilot Safety Act of 2018”) of Public Law 115–254, The FAA Reauthorization Act of 2018 (the Act), Congress directed the FAA to “revise section 61.3(c) of Title 14, Code of Federal Regulations (relating to second-class medical certificates), to apply to an operator of an air balloon to the same extent such regulations apply to a pilot flightcrew member of other aircraft.”

B. National Transportation Safety Board Recommendations

The NTSB made two Safety Recommendations in response to the 2016 Heart of Texas accident. Safety Recommendation A–17–034 urged the FAA to “Remove the medical certificate exemption in 14 [CFR] 61.23(b) for pilots who are exercising their privileges as commercial balloon pilots and are receiving compensation for transporting passengers.” Safety Recommendation A–17–045 urged the FAA to “analyze your current policies, procedures, and tools for conducting oversight of commercial balloon operations in accordance with your Integrated Oversight Philosophy, taking into account the findings of this accident; [and] based on this analysis, develop and implement more effective ways to target oversight of the operators and operations that pose the most significant safety risks to the public.”

The FAA agreed with the safety benefits of Safety Recommendation A–17–034⁸ and stated its intention to add the recommended change to its rulemaking agenda. The FAA responded to Safety Recommendation A–17–045⁹ by initiating a plan to develop and implement more effective ways to target oversight of operators posing the most significant safety risk to the public. The FAA identified and increased surveillance on the operators of the largest classes of balloons using information obtained from the Civil Aviation Registry, repair stations, and industry.

C. Summary of the NPRM

The FAA proposed amending the exception to hold a medical certificate for balloon pilots in § 61.3(c)(2)(vi) by limiting it to certain types of balloon operations. Specifically, the FAA proposed that any person holding a pilot certificate with a balloon class

rating and exercising the privileges of a private pilot certificate in a balloon; or providing flight training in a balloon in accordance with § 61.133(a)(2)(ii) is not required to hold a medical certificate. As a result of the amendment, the general requirement in § 61.3(c)(1) for a person to hold a medical certificate to serve as a pilot flight crewmember would apply to balloon pilots conducting operations for compensation or hire in a balloon (other than flight training) to hold a medical certificate issued under part 67.

Section 61.23 sets forth the specific requirements for when a particular class of medical certificate is required. Under § 61.23(a)(2)(ii), a second-class medical certificate generally is required when exercising the privileges of a commercial pilot certificate. Currently, under § 61.23(b)(3), a second-class medical certificate is not required when exercising the privileges of a pilot certificate with a glider category rating or balloon class rating in a glider or balloon, as appropriate.

First, the NPRM proposed to amend § 61.23(a)(2) to add a requirement for any person exercising the privileges of a commercial pilot certificate for compensation or hire in a balloon to hold a second-class medical certificate. Second, the NPRM proposed to remove the allowance in § 61.23(b) by specifying that a medical certificate is not required when exercising the privileges of a private pilot certificate with a balloon class rating in a balloon or when a person is exercising the privileges of a commercial pilot certificate with a balloon class rating in a balloon and providing flight training in accordance with § 61.133(a)(2)(ii).

Section 61.23(d) includes a table providing the duration for each class of medical certificate depending on several factors, including the medical certificate privilege that is being exercised. In order to maintain consistency with other medical certificate privileges in § 61.23(d), the NPRM proposed related amendments to the table of medical certificate durations at § 61.23(d)(1)(iii) and (d)(2)(i). Specifically, the NPRM proposed to add persons who are exercising the privileges of a commercial pilot certificate (other than for flight training) in a balloon to the established medical certificate duration table in § 61.23(d).

In addition, the NPRM proposed amendments to alleviate confusion and eliminate burdens for persons obtaining special medical flight tests and for persons operating under BasicMed.

First, the NPRM proposed amending §§ 61.3(c)(2) and 61.23(b) to allow persons to act as PIC during a special

medical flight test authorized under part 67 without holding a medical certificate. Second, the NPRM proposed amending several sections to alleviate certain burdens that resulted from the BasicMed final rule. Specifically, the NPRM proposed amending §§ 61.3(c)(2)(xiv), 61.23(c)(3)(i)(C) through (E), 61.113(i), 68.3(a) and (b), and 68.9(a) by expanding the requirements to allow required pilot flightcrew members to operate under BasicMed in addition to those individuals acting as PIC.

D. General Overview of Comments

The FAA considered 192 comments received during the 60-day public comment period. Of the comments received, 15 were out of scope, 17 were generally supportive of the proposed rule, and 112 generally opposed the rule as proposed. A significant number of commenters (142 commenters) suggested changes to the proposed rule. The remaining comments expressed neither support nor opposition to the rule. The majority of commenters were individuals. Two industry advocacy organizations submitted comments, as well as the NTSB.

IV. Discussion of Comments and the Final Rule

This rule amends part 61 to require a person who holds a commercial pilot certificate with a lighter-than-air category and balloon class rating to hold a valid second-class medical certificate when exercising the privileges of that certificate in a balloon for compensation or hire, unless that person is conducting flight training in accordance with § 61.133(a)(2)(ii).

Specifically, the exception in § 61.3(c)(2)(vi) is amended to reflect that any person holding a pilot certificate with a balloon class rating who is exercising the privileges of a private pilot certificate in a balloon; or providing flight training in a balloon in accordance with § 61.133(a)(2)(ii) is not required to hold a medical certificate. By revising the exception in § 61.3(c)(2)(vi), balloon pilots conducting operations for compensation or hire in a balloon (other than flight training), such as carrying passengers or property and advertising operations, are required under § 61.3(c)(1) to hold a medical certificate issued under part 67.

Further and for consistency across the regulations, the FAA is amending § 61.23(a)(2) to require any person exercising the privileges of a commercial pilot certificate for compensation or hire in a balloon, except when conducting flight training, to hold a second-class medical

⁸ NTSB Safety Recommendation A–17–034 https://www.nts.gov/_layouts/ntsb.recsearch/Recommendation.aspx?Rec=A-17-034.

⁹ NTSB Safety Recommendation A–17–045 https://www.nts.gov/_layouts/ntsb.recsearch/Recommendation.aspx?Rec=A-17-045.

certificate; and § 61.23(b) to remove the allowance to exercise the privileges of a balloon pilot certificate without a medical certificate. Additionally, the FAA adds an exception at § 61.23(b)(4)–(5) to explain under what circumstances balloon operations are excepted from the requirement to hold a second-class medical certificate.

A. Application of Medical Certificate Requirement to Operations Based on Size of Envelope or Passenger Capacity

Seventy-two commenters recommended that the proposed rule should only apply to certain operations based on size of envelope or number of people in the basket. Commenters proposed a passenger threshold ranging from 3 or more to 8 or more people. The Balloon Federation of America (BFA) stated that “any medical requirement for commercial balloon pilots should be limited to those operating balloons of such size as to legally transport 6 or more passengers.” Other commenters described the threshold as balloons with envelopes with volumes ranging from 77,682 cubic feet to 180,000 cubic feet.

Many of the commenters emphasized that these thresholds separated small-scale commercial balloonists from large-scale professional balloon ride operators. A common sentiment among commenters was that small commercial balloon operators were being over-regulated as a result of mishaps from larger balloon operators. Some commenters suggested that the NTSB safety recommendations were specifically directed toward the safety of larger passenger-carrying balloons.

The FAA notes that the second-class medical certification requirement represents a minimum safety standard for commercial operations. For non-air carrier operations, the regulatory requirements for medical certification do not vary based on the number of passengers aboard the aircraft or the size of the balloon. The FAA has long held that a passenger who engages with an aircraft operator in common carriage has a higher expectation of safety and oversight. The FAA notes that while operators of smaller balloons generally carry fewer passengers per year, the risk to any individual passenger in a smaller balloon is not significantly different than the risk to which they are exposed in a larger balloon.

The FAA does not concur with the assertion that the NTSB safety recommendations were specifically directed toward the safety of larger passenger-carrying balloons. Recommendation A–17–034 recommends that the FAA “remove the medical certification exemption in 14

Code of Federal Regulations 61.23(b) for pilots who are exercising their privileges as commercial balloon pilots and are receiving compensation for transporting passengers.” The FAA notes that while the NTSB directed the recommendation towards operations receiving compensation for transporting passengers, the NTSB did not distinguish between classes of operators in terms of size or passenger carrying capacity. Likewise, Congress included no distinction based on size or passenger-capacity in Section 318 when it directed the FAA to remove the exception from medical certification for commercial balloon pilots.

Accordingly, this medical certification requirement will apply to all holders of a commercial pilot certificate with a lighter-than-air category balloon class rating when exercising the privileges of that certificate in a balloon for compensation or hire, unless that person is conducting flight training, regardless of the size of the aircraft or the number of passengers carried.

B. Application of Rule to Commercial Balloon Operations Without Passengers

The medical certification requirement in this final rule does not provide an exception to commercial operations not involving the carriage of passengers.

Several commenters contended that commercial balloon operations that do not involve the carriage of passengers for compensation or hire should not require the PIC to hold a second-class medical certificate. BFA stated that “there is no more risk to the flying public in these activities, which include commercial advertising contract flying and special shape flying, than private ballooning for sport.” The BFA strongly opposed the inclusion of commercial operations that do not conduct paying passenger activities.

Commenters to the proposed rule provided multiple examples of how commercial operations frequently occur without passengers. For example, one commenter operates a one-of-a-kind specially shaped balloon that is hired by events for its uniqueness and popularity. The city of Albany Parks & Recreation noted that the proposed rule would have a significant impact on their ability to recruit pilots for their annual festival. This commenter noted that “the second-class medical requirement may significantly impact the number of balloons available for the festivals as some pilots may decide to forego the expense and trouble.”

Another commenter said that many companies incorporate balloons into their marketing strategies, noting that

these balloons are utilized as portable billboards to either be displayed while tethering on the ground or while conducting promotional flights during balloon festivals. One commenter observed that some events exclude private pilots from attending “since they interpret that getting your room, show up money or propane as ‘compensation’.”¹⁰

Section 318 of the FAA Reauthorization Act of 2018 directed the FAA to “revise section 61.3(c) of title 14, Code of Federal Regulations (relating to second-class medical certificates), to apply to an operator of an air balloon to the same extent such regulations apply to a pilot flightcrew member of other aircraft.”

The FAA proposed this rule specifically to implement section 318 of the FAA Reauthorization Act of 2018. Accordingly, the FAA proposed a requirement that any person exercising the privileges of a commercial pilot certificate for compensation or hire in a balloon, except when conducting flight training, hold a second-class medical certificate. The proposed rule made no distinction regarding whether the affected operation involved the carriage of passengers for compensation or hire, instead describing affected operations as including, but not limited to, operations for purposes of passenger sightseeing, aerial advertising, maintenance test flights, and research and development flights.

FAA regulations require a second-class medical certificate for all commercial pilots of fixed-wing aircraft and rotorcraft, regardless of whether the operation involves the carriage of passengers. Further, the statute does not allow an exception for commercial operations not involving the carriage of passengers. Therefore, in accordance with the express statutory language in Section 318 of the FAA Reauthorization Act of 2018, the FAA will require all commercial balloon pilots to hold a

¹⁰ The FAA notes that compensation for display of an aircraft from the ground does not constitute a commercial operation. See Legal Interpretation to Karen Torres (March 17, 2011). A balloon operator may be compensated for attending an event and displaying a balloon, including inflating the envelope while the aircraft remains on the ground. An operation is generally considered a commercial operation when the operator is compensated to fly the aircraft, with or without passengers. Further, a balloon pilot may exercise private pilot privileges to fly the balloon at an event he or she received compensation for attending, provided the compensation was not provided with the expectation that the operator fly the balloon during the event. See Legal Interpretation to Tucker Comstock (Sept. 8, 1977); see also Legal Interpretation to Gary Bruce Eaton (Dec. 7, 2012).

second-class medical certificate, as proposed in the NPRM.¹¹

C. Drug and Alcohol Testing

As discussed in the NPRM, the FAA considered whether to expand the definition of an operator under § 91.147 to include commercial balloon operations carrying passengers for compensation or hire. Doing so would have created a new requirement for such operators to obtain a Letter of Authorization (LOA) from the FAA, which would include a requirement to implement drug and alcohol testing programs in accordance with 14 CFR part 120. The FAA specifically sought comment on whether drug and alcohol testing should be required for commercial balloon operations.

Several commenters noted that the rule is insufficient because it lacks drug and alcohol testing. Most of the commenters expressing this sentiment used it as a rationale for opposing the rule, pointing out that holding a medical certificate does not compel a person to be randomly tested for prohibited substances and, as such, would have done little to prevent the Lockhart, Texas and Albuquerque, New Mexico¹² accidents.

The FAA considered this alternative and concluded that such a requirement goes beyond the scope of the statutory mandate. The FAA established the § 91.147 provision in the 2007 National Air Tour Safety Standards final rule¹³ following a pattern of accidents in powered aircraft. In that rule, the FAA specifically excluded balloon operations. The FAA notes that any future revisions of National Air Tour Safety Standards will require a risk-based assessment of need based on available safety data.

While medical certification under part 67 does not include a drug and alcohol testing component, it does require the applicant to authorize the FAA to access the applicant's National Driver Register (NDR) records. The NDR Problem Driver Pointer System (PDPS) identifies records on individuals whose privilege to operate a motor vehicle has been revoked, suspended, canceled or denied, or who have been convicted of

serious traffic-related offenses. Even if the applicant fails to disclose these convictions on the medical certificate application, the FAA receives a report from the NDR, providing an additional safeguard and mechanism for verifying the accuracy of the information provided by the airman.

In the case of the pilot of the Lockhart accident, the accident pilot had a 20-year history of drug and alcohol convictions. Even if the airman had omitted his history of traffic offenses on an application for a medical certificate, the FAA would likely have been made aware of the motor vehicle actions from NDR records and had the opportunity to deny the application for a medical certificate based on evidence of substance dependence or substance abuse, in accordance with §§ 67.207(a)(4), 67.207(b), 67.107(a)(4), and 67.107(b).

Accordingly, this final rule does not set forth a regulatory requirement for commercial balloon operators and pilots to implement a drug and alcohol testing program at this time.

D. Miscellaneous Issues

Whether Commercial Ballooning Poses a Risk Significant Enough To Warrant Additional Regulation

Multiple commenters stated that ballooning is an insignificant activity in the National Airspace System (NAS) and should not be subject to additional regulation.

The FAA does not consider commercial ballooning an insignificant activity. The FAA notes that the Lockhart, Texas and Albuquerque, New Mexico accidents demonstrate that ballooning is not insignificant, and the potential risk for catastrophic accidents is not insignificant. While the FAA concurs with commenters who asserted that balloon operations represent a small percentage of the total operations in the NAS, the FAA notes that balloons are frequently used for carrying passengers for compensation and present a risk that justifies a level of medical oversight equivalent to that of pilots of powered aircraft for certain operations such as commercial sightseeing operations. Further, the NTSB and Congress have identified this risk and called on the FAA to extend the requirements for medical certification to balloon pilots operating for compensation or hire.

Effects to the Industry Due to the Cost and Ability To Comply With the Rule

A number of commenters expressed concerns that the final rule would greatly reduce the number of balloon

pilots due to costs associated with obtaining a second-class medical certificate. The FAA acknowledges that in some cases, some commercial operators—particularly low-volume commercial operators—may opt to no longer conduct commercial operations due to the cost of obtaining a medical certificate outweighing the marginal economic benefit of conducting operations for compensation. While some pilots may leave the industry, other balloon pilots may opt to enter the commercial balloon industry to fill the void left by departing commercial pilots.

While the FAA does not expect a significant decrease in the availability of balloon pilots, changes in supply of balloon pilots could affect prices as well. The regulatory economic analysis does not quantify any potential changes in consumer and producer surplus from changes in supply. If the rule effectively screens out certain individuals for disqualifying medical conditions as intended, any potential adverse effects on individual applicants should be offset by the safety gains to the public. Nevertheless, the cost to obtain a second-class medical certificate is unlikely to be the sole reason to cause a commercial balloon pilot to discontinue commercial operations. The FAA estimates the cost per pilot to obtain a second-class medical certificate would be between \$160 and \$685 annually, depending on whether a special issuance would be necessary. This amount equates to about 0.06% to 0.37% of average annual revenues for small entities.¹⁴

The opportunity cost (including the time and fees) of seeking a second-class medical certification for some pilots may outweigh the monetary gains of operating commercially, resulting in some pilots opting not to seek medical certification. The FAA does not have sufficient information to predict how the supply of commercial balloon pilots would change as a result of this rule.

Multiple commenters stated that following the Heart of Texas accident, the ballooning insurance providers have required all commercial pilots flying balloons larger than 120,000 cubic feet to hold a second-class medical certificate. The revised regulatory economic analysis has factored in roughly 8.8% out of 4,869 commercial pilots with balloon class ratings who probably fall into this group, based on 2021 data from the Airmen Certification Database. The intent of the rule is to provide safety protection for all balloon

¹¹ The FAA excluded flight training because the legislation directed that the FAA to apply medical certification to commercial balloon pilots to the same extent as commercial pilots of other aircraft. The FAA has historically treated medical certification for persons conducting flight training different from other commercial operations.

¹² On June 26, 2021, the pilot and 4 passengers of a balloon were killed in an accident in Albuquerque, New Mexico. The accident is currently under investigation by the NTSB. (NTSB Accident No. WPR21FA242).

¹³ 72 FR 19382, Apr 18, 2007.

¹⁴ See Final Regulatory Flexibility Analysis discussed later in this preamble.

passengers, not just passengers flying with companies operating larger balloons.

Treatment of Balloon Operations for Compensation or Hire as Commercial Aviation Operations

Commenters acknowledged that, while they do receive compensation, they do not consider themselves “commercial” in a traditional sense. Many commenters used examples of being offered limited compensation in the form of lodging or fuel to participate in ballooning events, often without the expectation to carry passengers. Several commenters noted that many commercial operators only occasionally conduct operations for compensation or hire and do so to subsidize the cost of ballooning.

The concept of conducting commercial operations for compensation or hire for the purpose of defraying the cost of flying is not unique to ballooning. The FAA has long held that when a passenger responds to an offer made by an operator to the public to provide an aeronautical service in exchange for receipt of anything of value that is contingent on the pilot operating the aircraft, the public expects a higher level of oversight and safety assurance. The FAA does not delineate the volume of passenger activity for purposes of defining medical eligibility requirements.

The FAA notes that there are certain circumstances in which a pilot may accept limited compensation for operating an aircraft when exercising private pilot privileges. These exceptions are enumerated in § 61.113(b) through (h). Balloon pilots exercising private pilot privileges may share expenses with passengers under § 61.113(c), provided those expenses are limited to items such as fuel, oil, airport expenditures, or rental fees. Further, a pilot sharing expenses under § 61.113(c) may not pay less than the pro rata share of the operating expenses, and must not engage in common carriage by “holding out” to the public.

Suggestions for Alternative Methods of Establishing Medical Eligibility

Several commenters suggested alternative methods of meeting medical eligibility requirements. A few commenters suggested the FAA should allow BasicMed in lieu of a second-class medical certificate for commercial balloon operations. Multiple commenters proposed to allow state division of motor vehicle (DMV) record checks or NDR checks in lieu of medical certificate requirements. Finally, commenters suggested the medical

certificate requirement not be applied to existing commercial pilot certificate holders.

The FAA does not support allowing balloon pilots exercising commercial pilot privileges to establish medical eligibility under BasicMed. Section 318 of the 2018 FAA Reauthorization Act directed the FAA to revise regulations relating to second-class medical certificates to apply to commercial balloon pilots to the same extent such regulations apply to pilots of other aircraft.

Section 2307 of the FAA Extension, Safety, and Security Act of 2016 directed the FAA to issue or revise regulations to establish physical examination and education requirements, resulting in BasicMed. BasicMed was intended by statute to serve as an alternative means of establishing medical eligibility for limited non-commercial operations by persons exercising the privileges of a private pilot certificate. Section 2307 specifically excluded operations conducted for compensation or hire and specifically prohibited passenger or property carried for compensation or hire.

The FAA does not concur with the suggestion that the FAA implement motor vehicle record checks for commercial balloon pilots instead of a second-class medical certificate requirement. A motor vehicle record alone provides an incomplete picture of a person’s medical history and does not provide enough information to determine whether that person has a medical condition that would prevent him or her from safely operating an aircraft. Further, the medical eligibility requirements to hold a driver’s license are not consistent from state to state and, therefore, may not be sufficient to ensure the safety of pilots operating a balloon carrying passengers for compensation or hire.

When applying for a medical certificate in MedXPress, an applicant authorizes the NDR, through a designated State Department of Motor Vehicles, to furnish to the FAA information pertaining to his or her driving record consistent with 49 U.S.C. 30305(b)(3). The NDR PDPS identifies records on individuals whose privilege to operate a motor vehicle has been revoked, suspended, canceled or denied, or who have been convicted of serious traffic-related offenses.

NDR checks are just one part of the medical screening process and are insufficient alone to screen for disqualifying medical conditions. A person’s motor vehicle arrest record reveals only the times an individual was

arrested while operating a motor vehicle under the influence of alcohol or another drug. Further, an NDR check alone would not reveal evidence of a substance abuse problem if the applicant does not operate a motor vehicle while intoxicated. Most substantially, an NDR check alone would not uncover the myriad of potential non-substance abuse-related medical conditions that are evaluated in conjunction with a medical examination conducted under part 67.

The FAA does not consider the concept of excluding existing commercial pilot certificate holders from having to comply with a medical certificate requirement to be in the interest of flight safety. Existing commercial pilot certificate holders pose a similar medical risk to the NAS as new commercial pilot certificate holders. Such an exception for existing commercial pilots would remove this group from the safety benefit of medical certification without any additional medical risk mitigation.

Insurance Requirements

Commenters contended the rule is unnecessary because commercial insurers already require medical certificates. One commenter reported that insurance companies now require second-class medical certification for pilots of large passenger-carrying hot air balloons. The commenter added that the insurance requirement makes the proposed rule redundant and unnecessary.

Commercial balloon operators are not required by regulation to be insured, so withholding a regulatory requirement to hold a medical certificate and relying on insurance companies and operators to comply voluntarily with the insurance requirements would be insufficient alone to address the need for additional oversight of airmen conducting balloon operations for compensation or hire.

The FAA notes that commercial insurance requirements are not uniform and apply only to operators who choose to obtain such coverage and comply with the policy conditions. Further, insurance requirements for a medical certificate are not universal. Insurance providers typically require medical certificates for the pilots of commercial operations that are larger in terms of passenger capacity and number of operations.

Focus on FAA Enforcement

Commenters noted that the FAA should focus on enforcement of existing rules and/or surveillance for balloon operators, rather than put forward new

regulations requiring medical certification.

The FAA establishes regulatory standards to ensure safe operations in the NAS. The FAA's system is largely based on, and dependent upon, a culture of compliance with regulatory standards within the regulated community. FAA personnel use compliance, administrative, or legal enforcement actions to uphold the public's safety interest in ensuring that all regulated persons conform their conduct to statutory and regulatory requirements.

The FAA applies risk-based analysis to determine how, when, and where oversight and surveillance activities take place. The Integrated Oversight Philosophy allows both certificate holders and non-certificate holders to work with the FAA to ensure corrective action is appropriate and aims to address the root cause(s) of safety issues. Using this philosophy, the FAA oversight focus has been on existing surveillance, education, and awareness to the entire balloon industry to reduce the accident rate and improve balloon safety.

Comparison of Balloon and Glider Operations

Multiple commenters noted that the FAA stated in the NPRM that gliders were out of scope because they carried only 1 or 2 passengers. The commenters argued that based on the FAA's rationale, balloons that carry 2 passengers or less should be excluded as well.

The FAA proposed this rule specifically to implement section 318 of the FAA Reauthorization Act of 2018 and respond to NTSB Safety Recommendation A-17-034, which recommended that the FAA remove the medical certification exemption in part 61 for commercial balloon pilots receiving compensation for transporting passengers. Section 318 directed the FAA to revise regulations as they relate to operators of balloons. The FAA considered whether glider operations conducted for compensation or hire should be included in the scope of this rule. The FAA ultimately determined that as a category of aircraft, the safety record and general operational risk profile of gliders carrying passengers for compensation or hire did not warrant further regulatory oversight concerning the medical suitability of commercial glider pilots.

Efficacy of Medical Certificate Requirement

Several commenters expressed doubt that a medical certification requirement

will reduce the accident rate of commercial balloon operations. Commenters noted that inflight medical incapacitation is rare, and the FAA medical standards do not address the operational considerations of ballooning versus other aircraft. They contended the FAA lacks sufficient data to support a medical certification requirement. Further, they contended that a medical certificate requirement would not have affected the outcome of the two most recent significant fatal commercial accidents in Lockhart, Texas and Albuquerque, New Mexico.

The FAA is statutorily mandated to establish standards necessary to determine that an airman is physically able to perform the duties related to the privileges of their pilot certificate. See 49 U.S.C. 44703. Further, the FAA is statutorily mandated to revise regulations related to second-class medical certificates to apply to commercial balloon pilots.

In regards to whether medical standards address the operational considerations of ballooning, the FAA notes that medical certification standards address multiple dimensions of medical qualification, including medical factors that could diminish judgment and decision-making in addition to sudden physical incapacitation. While the standards do not apply to any specific type of aircraft operation, the standards do address general categories of medical considerations that are applicable to balloon operations. These categories include: vision; ear, nose, and throat; equilibrium; mental; neurological; cardiovascular; and general health. The standards established under part 67 are minimum standards. However, the Federal Air Surgeon does have the discretion to authorize special issuance of a medical certificate or a Statement of Demonstrated Ability (SODA), which offers flexibility for the FAA to issue a medical certificate based on the individual circumstances of an applicant.

As noted in the proposed rule, the 2016 Lockhart accident served as an example of how a lack of medical oversight allowed the pilot to continue to operate a balloon for compensation or hire in spite of a questionable medical history. While instances of sudden inflight incapacitation are rare, there are documented cases of events occurring. Medical incapacitation incidents are often not reported if no accident occurred. When an accident does occur, it can be difficult to pinpoint whether medical issues of the pilot were a factor, as evidence is often limited to the pilot's available medical records, postmortem

toxicology and autopsy reports. Consequently, it is difficult to quantify the impact of medical factors on aviation safety.

While medical certification cannot completely mitigate the risk of an accident due to a medical condition of the pilot, the public holds an expectation for a higher level of operational oversight when the flight is conducted for compensation or hire. One method the FAA has to accomplish this objective is medical certification.

Medical Certificates for All Balloon Operations

One commenter suggested that medical certificates should be required for all balloon operations.

The FAA will not extend the medical certificate requirement to balloon pilots exercising private or sport pilot privileges. Non-commercial balloon operations are among the lowest-risk operations in the NAS and do not warrant the additional regulatory burden of medical certification requirements. While pilots exercising the privileges of a private pilot or sport pilot certificate in a balloon are not required to hold a medical certificate, they must comply with the 14 CFR 61.53(b) requirement to abstain from operating an aircraft while that person knows or has reason to know of any medical condition that would make that person unable to operate in a safe manner. In addition, these pilots have fewer privileges, and in the case of sport pilots, more operational restrictions, than a commercial pilot holding his or her flight services out to the public for compensation. The FAA has determined that compliance with a prohibition from operating an aircraft during a medical deficiency sufficiently mitigates the risk of an accident in a balloon due to a medical-related issue in an operation exercising private or sport pilot privileges.

E. Effective Date

Commenters recommended the FAA should delay the effective date of the medical certificate requirement provision beyond 180 days. Most of those comments suggested that the rule take effect one year after publication. Commenters cited a lack of Aviation Medical Examiners (AMEs), the ongoing COVID-19 public health emergency, and delays in processing applications by the FAA.

Multiple commenters expressed concern that there are delays in processing medical certificate applications if a special issuance is required, preventing applicants from complying with the rule within 180

days. The BFA asserted that the process of obtaining a special issuance is burdensome and may take months, or in some cases years, to obtain a medical certificate.

The FAA proposed in the NPRM that compliance with the medical certificate requirement become effective 180 days from publication of the final rule. This would provide sufficient time for the majority of affected persons to comply with this rule by obtaining a medical certificate prior to the effective date. For reasons explained below, the medical certificate requirement will go into effect on May 22, 2023, 180 days after publication of this rule.

Based on historical data, the FAA estimates that over 95% of applicants, including those who need a special issuance, will have a disposition within 150 days. Approximately 1% of all applicants for FAA medical certificates are issued a denial. Of those denials, 95% of the final dispositions resulted from a lack of response to FAA requests for additional information. Only 4% of applicants take over 150 days for certification. Many of these individuals have medical conditions, which require mandatory periods of observation to demonstrate stability and/or allow for the risk of recurrence to diminish.

The FAA acknowledges that pilots with certain medical conditions may be required to obtain additional evaluation(s) prior to issuance of a medical certificate. The FAA recommends that affected airmen, especially those with known health conditions, initiate the process to apply for a medical certificate in a timely manner, taking into consideration the time needed to obtain relevant medical information and the time necessary for the FAA to review. Individuals who delay applying for a medical certificate risk loss of some operating privileges due to the inability to comply with the requirement to hold a second-class medical certificate.

Several commenters noted that the ongoing COVID-19 public health emergency would affect the ability of balloon pilots to obtain a medical certificate within 180 days. These commenters noted that there is a limited availability of health care workers due to COVID-19.

Commenters did not provide evidence that COVID-19 continues to limit the access to AMEs. While initial response to COVID-19 did result in significant restrictions and more limited access to healthcare facilities and physicians, access to AMEs has since returned to pre-pandemic levels.

Multiple commenters noted that balloon pilots never had medical

certification requirements prior to this rule. BFA noted that a significant proportion of commercial balloon pilots are older and at an age where they likely have one or more medical conditions requiring a special issuance.

Accordingly, commenters suggested that, as a population, balloon pilots will require more time to obtain a medical certificate.

The FAA notes that, as a group, older pilots are more likely to have medical conditions that need additional evaluation. The FAA does not have evidence to support the assertion that balloon pilots are as a population older than other pilots.

Multiple commenters noted a lack of available AMEs. One commenter noted that there was only one AME serving Albuquerque, New Mexico.

The FAA notes that at the time of publication of the final rule, AMEs were practicing at 2,056 locations across the United States, including 13 locations in New Mexico. Of the 11 AMEs practicing at 13 locations in New Mexico, six were practicing in Albuquerque.¹⁵

In the NPRM, the FAA proposed that the two miscellaneous amendments be made effective 30 days after publication of the final rule. No comments were received regarding the effective date of either miscellaneous amendment. Accordingly, both provisions will become effective on December 22, 2022, 30 days after publication of this rule.

F. Comments Regarding Miscellaneous Amendments

The FAA received generally supportive comments from individual commenters and the Aircraft Owners and Pilots Association in regard to the two miscellaneous amendments in the NPRM. The proposal to remove the requirement for a medical certificate in order to act as PIC in a special medical flight test received two supporting comments. Accordingly, the FAA is implementing the amendments as proposed. To allow persons to act as PIC during special medical flight tests, the FAA is amending § 61.3(c)(2) by adding new paragraph (xv), which allows persons to act as PIC during authorized special medical flight tests without holding a medical certificate. The FAA also adds a parallel provision in § 61.23(b)(12).

The proposal to extend BasicMed to persons serving as required flightcrew members but not acting as PIC received ten supporting comments. Accordingly, the FAA is implementing the

amendments as proposed. Specifically, the FAA is amending §§ 61.3(c)(2)(xiv), 61.23(c)(3)(i)(C) through (E), 61.113(i), 68.3(a) and, 68.3(b), and 68.9(a) by expanding the requirements to include required pilot flightcrew members.

V. Regulatory Notices and Analyses

Federal agencies consider impacts of regulatory actions under a variety of executive orders and other requirements. First, Executive Order 12866 and Executive Order 13563 direct that each Federal agency shall propose or adopt a regulation only upon a reasoned determination that the benefits of the intended regulation justify the costs. Second, the Regulatory Flexibility Act of 1980 (Pub. L. 96-354) requires agencies to analyze the economic impact of regulatory changes on small entities. Third, the Trade Agreements Act (Pub. L. 96-39) prohibits agencies from setting standards that create unnecessary obstacles to the foreign commerce of the United States. Fourth, the Unfunded Mandates Reform Act of 1995 (Pub. L. 104-4) requires agencies to prepare a written assessment of the costs, benefits, and other effects of proposed or final rules that include a Federal mandate that may result in the expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of \$100,000,000 or more (adjusted annually for inflation) in any one year. The current threshold after adjustment for inflation is \$165 million, using the most current (2021) Implicit Price Deflator for the Gross Domestic Product.

In conducting these analyses, the FAA has determined that this rule: will result in benefits that justify costs; is not a “significant regulatory action” as defined in section 3(f) of Executive Order 12866; may have a significant economic impact on a substantial number of small entities; will not create unnecessary obstacles to the foreign commerce of the United States; and will not impose an unfunded mandate on State, local, or tribal governments, or on the private sector.

A. Regulatory Impact Analysis

Benefits and Costs of This Rule

The final rule will generate costs for balloon pilots to obtain a second-class medical certificate and for some pilots to seek authorization through special issuance. There is a separate cost for the FAA to implement this requirement in terms of reviewing and processing submissions related to medical certification. The FAA estimates the present value of total costs over ten years is \$2.4 million to \$16.3 million

¹⁵ FAA Designee Management System, as of Oct 17, 2022. <https://designee.faa.gov/#/designeeLocator>.

with a mid-estimate of \$6.9 million at a 7 percent discount rate, and \$2.9 million to \$19.9 million with a mid-estimate of \$8.4 million at a 3 percent discount rate. The FAA estimates the annualized costs over ten years is \$0.3 million to \$2.3 million with a mid-estimate of \$1.0 million at a 7 percent discount rate and \$0.3 million to \$2.3 million with a mid-estimate of \$1.0 million at a 3 percent discount rate. While lack of data on the effectiveness of the rule prevents quantification of benefits, the FAA anticipates the rule will enhance safety of commercial balloon operations, including reduced risks of accidents, fatalities, and injuries caused by medical impairment of balloon pilots. The FAA estimates that it would take between 0.3 to 2.8 averted fatalities in the next ten years for the benefits to breakeven with the costs of this rule.

In addition to the requirement for commercial balloon pilots to hold a second-class medical certificate, the rule made two miscellaneous amendments. The first amendment addresses certain inconsistencies in current regulations for conducting special medical flight tests and the second amendment addresses inconsistencies regarding who may operate under BasicMed. The FAA does not quantify the effects of the two miscellaneous amendments, but anticipates there will be minor cost savings. By allowing persons to receive special medical flight tests under part 67 without holding a medical certificate, the FAA aviation safety inspector will no longer have the burden of assuming the responsibility as PIC while conducting a medical test flight with an applicant. This also eliminates the inconsistency of both having to hold a medical certificate for the purposes of receiving a special medical flight test and needing the special medical flight test to obtain a medical certificate. The amendment to extend BasicMed eligibility to other required pilot flightcrew members reduces the burden for those pilots not acting as PIC of having to hold a medical certificate under current regulations and holds them to the same standard as those pilots acting as PIC under BasicMed. This may also result in more pilots seeking opportunities to serve as a safety pilot by lowering the medical certificate barrier without compromising safety. It also increases the number of pilots eligible to serve as safety pilot, easing the burden of pilots with instrument privileges conducting flights to meet recent flight experience requirements and consequently

increasing overall safety in the national airspace system.

Statement of Need

This rulemaking addresses the need for additional oversight of airmen conducting balloon operations for compensation or hire by implementing the statutory mandate under the Commercial Balloon Pilot Safety Act of 2018 and NTSB Safety Recommendation A-17-034 to extend second-class medical certification requirements to operators of balloons. As discussed elsewhere in this document, the 2016 Heart of Texas accident highlights the potential for a pilot's medical condition to pose safety risks, which are not necessarily less than that of powered aircraft sightseeing operations that require at least a second-class medical certificate (e.g., commercial transportation of skydivers, banner towing, or aerial photography). Following the 2016 Heart of Texas accident, there have been voluntary efforts by the industry to raise the standard for balloon pilots, notably through the Envelope of Safety Program. While incentives to ensure a certain level of safety exist in the private market for commercial balloon operations, it is unlikely in the absence of federal regulation that all balloon pilots would choose to comply with the requirements of a second-class medical certificate. At the same time, consumers may be insufficiently aware of the risks associated with balloon pilots operating under a lower standard to demand full compliance. Therefore, this rulemaking is necessary to achieve a higher level of safety for commercial balloon operations.

Data and Assumptions

This section summarizes key data sources and assumptions used throughout the analysis:

- Costs and benefits are estimated over 10 years.
- Costs and benefits are presented in 2021 dollars.
- The present value discount rate of seven and three percent is used, as required by the Office of Management and Budget.
- The cost for a medical examination fee with an AME is in the following range: Low = \$100, Mid = \$150 or High = \$200.¹⁶
- The hourly rate of a pilot (VPT) exercising their commercial balloon rating varies greatly. Therefore, the FAA

¹⁶ According to FAA subject matter experts and Phoenix East Aviation, <https://www.pea.com/blog/posts/the-faa-medical-exam-common-questions/>, the cost per medical exam ranges from \$100 to \$200.

used the following hourly wages: Low = \$15, Mid = \$31.50 or High = \$48.¹⁷

- Vehicle operating cost per mile (VOC) as determined by the Internal Revenue Service (IRS) is \$0.16.¹⁸
- The FAA assumes 1.5 hours to complete the MedXPress form.¹⁹
- The FAA assumes 1 hour to complete a medical examination.
- The FAA assumes 1 hour of travel time to and from an AME's office.

Affected Entities

At the time of writing, the FAA used 2021 data from the Airmen Certification database to identify pilots certificated as commercial balloon pilots. There are currently 4,869 commercial pilots with balloon class ratings. During the public comment period, the FAA learned that most insurance providers have required commercial pilots flying balloons larger than 120,000 cubic feet to hold a second-class medical certificate. FAA sources indicate that of the 4,869 commercial pilots with balloon class ratings, 427 balloon pilots (approximately 8.8% of total commercial balloon pilots) fall into this category.²⁰ Therefore, the updated estimated number of balloon pilots without medical certification in 2021 is 4,442.

This balloon class rating does not have an expiration date, and unlike certain other pilot ratings, a person exercising the privileges of a balloon class rating is not required to hold a valid first-, second-, or third-class medical certificate. Because of this, there is uncertainty in the number of commercial balloon pilots actively exercising commercial pilot privileges. For this reason, the FAA produced a low, mid, and high-range estimate of how many pilots would possibly be affected by this final rule.

In addition to the current number of certificated pilots with a commercial balloon rating, the FAA gathered data from the last 14 years to estimate an average growth of newly certificated commercial balloon pilots per year. Over the course of the last 14 years, from 2007 through 2020, there was, on

¹⁷ According to the FAA subject matter experts, responses from the Balloon Federation of America and online sources, the FAA estimates a commercial balloon pilot earns from \$15 to \$48 an hour. Online source: <https://www.jobmonkey.com/uniquejobs3/hot-air-balloon-pilot-jobs/>.

¹⁸ <https://www.irs.gov/newsroom/irs-issues-standard-mileage-rates-for-2021>. Accessed on April 21, 2021.

¹⁹ This estimate is consistent with FAA's estimated burden hours associated with the MedXPress form 8500-8 approved under OMB No. 2120-0034.

²⁰ FAA Airman Registry internal analysis as of July 2021.

average, 56 newly certificated commercial balloon pilots per year.

As mentioned earlier, there is uncertainty with the number of active pilots exercising their commercial balloon privileges. The FAA assumes a low estimate of 20%, a mid-estimate of 50% and a high estimate of 100% of the 4,442 impacted commercial pilots with a balloon class rating. Table 1 displays the potential number of airmen that would be affected by the final rule over the course of ten years. Note that in the first year and thereafter, the number of impacted commercial pilots includes an additional 56 newly certificated commercial balloon pilots each year to account for growth over time. Corresponding to the number of active balloon pilots is the number of expected application submissions for second-class medical certificates each year.

TABLE 1—LOW, MIDDLE AND HIGH ESTIMATES OF ACTIVE BALLOON PILOTS

Year	Low	Middle	High
1	944	2,277	4,498
2	1,000	2,333	4,554
3	1,056	2,389	4,610
4	1,112	2,445	4,666
5	1,168	2,501	4,722
6	1,224	2,557	4,778
7	1,280	2,613	4,834
8	1,336	2,669	4,890
9	1,392	2,725	4,946
10	1,448	2,781	5,002
Total	11,960	25,290	47,500

Benefits

The benefits of this rule come from the value of averted accidents attributable to pilots operating commercial balloons with medical deficiencies. While under current regulations, balloon pilots must comply with § 61.53(b), which states that “a person shall not act as pilot in command, or in any other capacity as a required pilot flight crewmember, while that person knows or has reason to know of any medical condition that would make the person unable to operate the aircraft in a safe manner,” the second-class medical certificate requirement would provide greater assurances of safety to balloon passengers and other balloon operations conducted for compensation or hire. By requiring balloon pilots to undergo a medical certification process, an AME will have the opportunity to identify potentially impairing medical conditions and treatments thereof to ensure sufficient mitigation of any associated risks.

To quantify the benefits from this rule, it is necessary to: (1) forecast a baseline level of accidents attributable to medically impaired balloon pilots in the absence of this rule and (2) estimate the extent to which the medical certification requirement effectively reduces the risk. Based on the FAA’s analysis of the NTSB accident database during the ten-year period from 2010–2020, the FAA finds that there has been one accident, the Heart of Texas accident, where the medical condition of the pilot was a factor. The Heart of Texas accident resulted in 16 fatalities. The commercial pilot and all 15 passengers were killed, and the balloon was destroyed by impact forces and post-crash fire. For an accident of this magnitude, the FAA estimates that the social cost associated with the loss of life alone is \$185.6 million using a value of statistical life of \$11.6 million.²¹ Additional costs of a similar accident would include non-fatal injuries, the value of property loss and damage as well as the cost of the accident investigation and clean-up efforts. However, the FAA currently does not have enough information to monetize those additional costs.

The FAA finds that the requirement for a second-class medical certificate could have prevented the Heart of Texas accident if: (1) information made available through the NDR database as part of the medical review process revealed the pilot’s history of drug- and alcohol-related traffic offenses and resulted in a disqualification, (2) a medical review either prompted effective treatment of or disqualification for the pilot’s medical conditions (depression and ADHD), or (3) discussion of the use of certain medications with an AME would have resulted in the pilot adjusting his behavior to avoid usage as a PIC during a balloon operation.

Due to the infrequency of such events and limitations in the available data, it is difficult to quantify and monetize the benefits of the rule. The FAA intended to update its estimates of quantified benefits for the final rule based on additional information and data identified during the comment period. Specifically, the FAA requested information and data, including references and sources that could be used to predict the number of similar accidents that may occur in the future and the number of accidents that may be

averted by this rule. No additional data was provided during the comment period.

While the FAA describes the benefits of the rule qualitatively, the FAA expects that second-class medical certification provides additional screening to reduce the risk of commercial balloon pilots operating while medically impaired. In the section below, the FAA conducted a breakeven analysis to show that the monetized benefits of the rule equates costs if it averts 0.3 to 2.8 fatalities in the next ten years.

Costs

This final rule results in private sector costs to balloon pilots for obtaining a second-class medical certificate, including the opportunity cost of time and fee for the medical exam with an AME. Some balloon pilots with certain health conditions that are otherwise disqualifying may also incur the cost of seeking a special issuance medical certificate or SODA. The FAA incurs costs for reviewing and processing the applications (*i.e.*, MedXPress forms) and reviewing NDR information for a subset of submissions.

Cost to Industry

(1) Costs of Obtaining Second-Class Medical Certification

To obtain a second-class medical certificate, an applicant needs to complete the MedXPress form and a medical exam with an AME. Because the second-class medical certificate expires 12 months after the date of the medical exam, the FAA assumes that pilots incur these costs on an annual basis. The FAA estimates the opportunity cost of time for each applicant would include 1.5 hours to complete the MedXPress form, 1 hour for the medical examination, and 1 hour of travel time to and from the exam for a total of 3.5 hours.²² The FAA assumes an hourly wage for a balloon pilot ranges from \$15 per hour to \$48 per hour, with a mid-estimate of \$31.50 per hour, to value time for the medical exam and completing the MedXPress form. For valuing travel time, the FAA uses an estimate of \$13.60 per hour consistent with 2016 DOT guidance (in this analysis, \$14.44 was used for year

²¹ Value of a statistical life in 2020 is \$11.6 million. See DOT published values at <https://www.transportation.gov/office-policy/transportation-policy/revised-departmental-guidance-on-valuation-of-a-statistical-life-in-economic-analysis>.

²² According to the “FAA Aerospace Medical Certification Services Airman Satisfaction Survey,” (April 2017), over 60 percent of applicants traveled between 0 and 25 miles one way for an exam with an AME. (Retrieved from: https://www.reginfo.gov/public/do/PRAViewDocument?ref_nbr=201904-2120-007).

2021).²³ Multiplying the value of time by the amount of time spent yields an estimate of \$51.94 to \$134.44, with a mid-estimate of \$93.19 per applicant in opportunity cost of time. FAA subject matter experts estimate the cost per medical exam with an AME ranges from \$100 to \$200, with an average of \$150. Additional costs arise from vehicle operating costs (VOC) of 16 cents per

mile for an average of 50 miles traveled by vehicle to and from a medical exam, which yields \$8 for each exam. Taking the sum of the value of time spent, medical exam fee, and VOC, the FAA estimates that each applicant incurs costs of approximately \$160 to \$342, with a mid-estimate of \$251 to obtain a second-class medical certificate each year.

Table 2 below shows the range of total costs to industry for obtaining a second-class medical certificate. The FAA derives the aggregated low, middle, and high costs by multiplying the estimated number of active pilots (low, middle, high) as shown in Table 1 by the corresponding low, middle, and high costs per applicant by cost category.

TABLE 2—COSTS TO INDUSTRY BY CATEGORY TO OBTAIN SECOND-CLASS MEDICAL CERTIFICATION

Year	Opportunity cost of time for exam, MedXPress form, and travel			Fee for medical exam with AME			Vehicle operating costs		
	Low	Middle	High	Low	Middle	High	Low	Middle	High
1	\$48,899	\$211,875	\$604,081	\$94,400	\$341,550	\$899,600	\$7,552	\$18,216	\$35,984
2	51,940	217,412	612,240	100,000	349,950	910,800	8,000	18,664	36,432
3	54,996	222,965	620,414	105,600	358,350	922,000	8,448	19,112	36,880
4	58,080	228,559	628,650	111,200	366,750	933,200	8,896	19,560	37,328
5	61,180	234,169	636,903	116,800	375,150	944,400	9,344	20,008	37,776
6	64,297	239,795	645,173	122,400	383,550	955,600	9,792	20,456	38,224
7	67,430	245,439	653,460	128,000	391,950	966,800	10,240	20,904	38,672
8	70,581	251,100	661,764	133,600	400,350	978,000	10,688	21,352	39,120
9	73,748	256,777	670,084	139,200	408,750	989,200	11,136	21,800	39,568
10	76,932	262,471	678,421	144,800	417,150	1,000,400	11,584	22,248	40,016

Note: The low, middle, and high estimates correspond to the low, middle, and high estimates of the number of active pilots and the range of costs per applicant in each category of costs.

(2) Cost of Obtaining a Special Issuance

For applicants that do not initially meet the requirements of a second-class medical certification, there may be an additional cost to seek a special issuance medical certificate or SODA.²⁴ The FAA assumes that an applicant

seeking special issuance would incur the same costs and time of a second-class medical certification as estimated per applicant above. Based on the historical rate of special issuances, the FAA assumes that approximately 10 percent of affected balloon pilots would seek special issuance, including SODAs.

Therefore, the FAA takes the sum of costs in each cost category for obtaining a second-class medical certification and multiplies by 0.1 to obtain the total industry cost for obtaining special issuances. Table 3 below shows the range of special issuance costs in each year.

TABLE 3—TOTAL INDUSTRY COST FOR SPECIAL ISSUANCES

Year	Total private sector costs for special issuance		
	Low	Middle	High
1	\$15,085	\$57,164	\$153,967
2	15,994	58,603	155,947
3	16,904	60,043	157,929
4	17,818	61,487	159,918
5	18,732	62,933	161,908
6	19,649	64,380	163,900
7	20,567	65,829	165,893
8	21,487	67,280	167,888
9	22,408	68,733	169,885
10	23,332	70,187	171,884
Present Value at 7%	131,272	441,519	1,136,479
Annualized at 7%	18,690	62,862	161,809
Present Value at 3%	161,857	540,060	1,385,536
Annualized at 3%	18,975	63,311	162,427

²³ Department of Transportation. "The Value of Travel Time Savings: Departmental Guidance for Conducting Economic Evaluations Revision 2 (2016 Update). Available at: [https://www.transportation.gov/office-policy/transportation-policy/revised-departmental-](https://www.transportation.gov/office-policy/transportation-policy/revised-departmental-guidance-valuation-travel-time-economic)

[guidance-valuation-travel-time-economic](https://www.transportation.gov/office-policy/transportation-policy/revised-departmental-guidance-valuation-travel-time-economic). This analysis assumes that the value of travel time grows 1% a year. Year 2021: 14.44.

²⁴ The cost to obtain a SODA is included in the estimated costs to obtain a special issuance medical

certificate. Based on the FY2022 data from Aerospace Medical Certification Division, the FAA estimates that on average approximately 0.02% (or no more than one applicant a year) of medical certificate applicants will require a SODA.

Summary of Total Cost to Industry

The FAA estimates the present value of total cost to industry associated with obtaining a second-class medical certification and special issuances to be \$1.4 million to \$12.5 million, with a mid-estimate of \$4.9 million at a 7 percent discount rate and \$1.8 million

to \$15.2 million, with a mid-estimate of \$5.9 million at a 3 percent discount rate. The annualized value of total cost to industry are \$0.2 million to \$1.8 million with a mid-estimate of \$0.7 million at a 7 percent discount rate and \$0.2 million to \$1.8 million with a mid-estimate of \$0.7 million at a 3 percent discount rate.

In Table 4 below, the FAA shows these total costs to industry for obtaining a second-class medical certification and special issuances in each year. The low, middle, and high estimates correspond to the range of estimates on the number of affected pilots and costs associated with obtaining medical certification.

TABLE 4—TOTAL INDUSTRY COSTS

Year	Total cost to industry		
	Low	Middle	High
1	\$165,936	\$628,805	\$1,693,632
2	175,934	644,629	1,715,419
3	185,949	660,470	1,737,223
4	195,993	676,355	1,759,096
5	206,056	692,259	1,780,987
6	216,138	708,182	1,802,897
7	226,237	724,122	1,824,825
8	236,356	740,082	1,846,772
9	246,493	756,059	1,868,737
10	256,648	772,056	1,890,721
Present Value at 7%	1,443,990	4,856,705	12,501,274
Annualized at 7%	205,592	691,486	1,779,900
Present Value at 3%	1,780,422	5,940,655	15,240,897
Annualized at 3%	208,720	696,426	1,786,698

Costs to FAA To Implement Requirement for Second-Class Medical Certification for Balloon Pilots

(1) FAA Cost of MedXPress Review and Processing

The FAA incurs costs associated with reviewing and processing applications

submitted through MedXPress. Based on internal FAA data on total personnel costs and benefits attributable to labor hours spent on review of airmen medical certification in FY 2019 through FY 2021, the FAA estimates an average cost of \$30 to review and

process each application. In Table 5 below, the Agency derives the FAA cost to review applications in each year using the estimated range for the number of submissions based on the forecasted number of active balloon pilots in each year.

TABLE 5—FAA COSTS TO REVIEW AND PROCESS APPLICATIONS

Year	FAA costs for review and processing		
	Low	Middle	High
1	\$27,944	\$67,402	\$133,146
2	29,601	69,060	134,804
3	31,259	70,717	136,462
4	32,917	72,375	138,119
5	34,574	74,033	139,777
6	36,232	75,690	141,435
7	37,890	77,348	143,092
8	39,547	79,006	144,750
9	41,205	80,663	146,408
10	42,863	82,321	148,065
Present Value at 7%	242,207	519,347	981,108
Annualized at 7%	34,485	73,943	139,688
Present Value at 3%	298,552	635,141	1,195,954
Annualized at 3%	34,999	74,458	140,202

(2) FAA Cost of Special Issuance Review

A MedXPress application that requires a special issuance medical certificate is deferred to the Aerospace Medical Certification Division (AMCD) for further consideration. Based on FAA internal data on personnel

compensation and benefits attributable to labor hours spent on reviewing and processing special issuance medical certificates in FY 2019 through FY 2021, the FAA estimates an average cost of approximately \$126 per special issuance review. The table below displays the

FAA cost for special issuance review assuming that 10 percent of the applicants do not initially qualify for second-class medical certification.

TABLE 6—FAA COST OF SPECIAL ISSUANCE REVIEW

Year	FAA costs for special issuance review		
	Low	Middle	High
1	\$11,931	\$28,779	\$56,851
2	12,639	29,487	57,559
3	13,347	30,195	58,267
4	14,055	30,903	58,974
5	14,763	31,611	59,682
6	15,470	32,318	60,390
7	16,178	33,026	61,098
8	16,886	33,734	61,806
9	17,594	34,442	62,513
10	18,302	35,150	63,221
Present Value at 7%	103,418	221,751	418,915
Annualized at 7%	14,724	31,572	59,644
Present Value at 3%	127,476	271,193	510,650
Annualized at 3%	14,944	31,792	59,864

(3) Cost of FAA Review of the National Driver Register (NDR) Reports

Included within the medical certificate application is the applicant's authorization for the FAA to receive NDR data, which provides a report of applicable motor vehicle actions within the preceding three years. Intentional failure to report required drug or alcohol motor vehicle actions is grounds for

suspension of a pilot certificate. NDR checks help to identify persons who may have substance abuse or dependence issues. Although the bulk of the process is automated, the FAA estimates there is roughly a 3% return rate that requires additional review and investigation. The FAA estimates that it takes approximately 40 hours of additional review time by a special

agent for each applicant that is flagged through the NDR database. Using a special agent hourly wage adjusted for fringe benefits of \$60.18, as shown in Table 7 below, the FAA estimates that each submission that requires further investigation would cost \$2,407. The total costs to FAA associated with NDR review are estimated in Table 8 using the range of estimated submissions.

TABLE 7—SPECIAL AGENT WAGE WITH FRINGE BENEFITS

	Yearly	Hourly	Fringe benefits	Total
Special Agent	\$91,877	\$44.17	\$16.01	\$60.18
Federal Fringe Benefit Factor ^{1 2 3}			36.25%	

¹ <https://www.whitehouse.gov/sites/whitehouse.gov/files/omb/memoranda/2008/m08-13.pdf>.

² Percent of position's basic pay.

³ Dallas-Fort Worth, TX-OK locality plus fringe benefits, GS-12 Step 4. Retrieved from <https://www.opm.gov/policy-data-oversight/pay-leave/salaries-wages/salary-tables/pdf/2021/DFW.pdf>.

TABLE 8—FAA COSTS FOR NDR REVIEW

Year	FAA costs for NDR review		
	Low	Middle	High
1	\$68,172	\$164,436	\$324,828
2	72,216	168,480	328,872
3	76,260	172,524	332,916
4	80,304	176,568	336,960
5	84,348	180,612	341,004
6	88,392	184,656	345,048
7	92,436	188,700	349,092
8	96,481	192,745	353,136
9	100,525	196,789	357,180
10	104,569	200,833	361,224
Present Value at 7%	590,895	1,267,013	2,393,537
Annualized at 7%	84,130	180,394	340,786
Present Value at 3%	728,356	1,549,507	2,917,681
Annualized at 3%	85,386	181,650	342,041

Summary of Total Costs to FAA

The total costs to the FAA to implement the requirement for commercial balloon pilots to hold a

second-class medical certificate is the sum of the costs for FAA review and processing of MedXPress applications, review of special issuances, and review

of NDR information associated with certain applications. The FAA estimates the present value of total costs to the Agency to be \$0.9 million to \$3.8

million, with a mid-estimate of \$2.0 million at a 7 percent discount rate and \$1.2 million to \$4.6 million, with a mid-estimate of \$2.5 million at a 3 percent discount rate. The annualized value of total cost to FAA is \$0.1 million to \$0.5

million with a mid-estimate of \$0.3 million at a 7 percent discount rate and \$0.1 million to \$0.5 million with a mid-estimate of \$0.3 million at a 3 percent discount rate.

The FAA acknowledges the difficulty in estimating FAA burden and cost after

the effective date of this rule given uncertainties in the number of pilot applicants and those pilots that would either receive a second-class medical certification or be granted a special issuance certification.

TABLE 9—TOTAL COSTS TO FAA

Year	Total cost to FAA		
	Low	Middle	High
1	\$108,047	\$260,617	\$514,825
2	114,456	267,027	521,235
3	120,866	273,436	527,644
4	127,276	279,846	534,054
5	133,685	286,256	540,463
6	140,095	292,665	546,873
7	146,504	299,075	553,282
8	152,914	305,484	559,692
9	159,323	311,894	566,102
10	165,733	318,303	572,511
Present Value at 7%	936,521	2,008,111	3,793,560
Annualized at 7%	133,339	285,910	540,118
Present Value at 3%	1,154,385	2,455,842	4,624,285
Annualized at 3%	135,329	287,900	542,107

Total Costs of the Rule

The total costs are shown in the table below, which includes both costs to industry and to the FAA. The total costs over the ten years include the costs for pilots to obtain their second-class medical certificate, special issuances and costs to the Agency for review of applications, special issuances, and NDR information. The FAA estimates the present value of total costs over ten years is \$2.4 million to \$16.3 million with a mid-estimate of \$6.9 million at a 7 percent discount rate and \$2.9 million to \$19.9 million with a mid-estimate of \$8.4 million at a 3 percent discount rate. The FAA estimates the annualized costs over ten years is \$0.3 million to \$2.3 million with a mid-estimate of \$1.0 million at a 7 percent discount rate and \$0.3 million to \$2.3 million with a mid-estimate of \$1.0 million at a 3 percent discount rate.

As stated previously, in some cases, where the airman's medical condition

does not meet the part 67 standard, the airman may still be issued a medical certificate by authorization for special issuance when the Federal Air Surgeon determines the risk associated with the medical condition(s) to be sufficiently mitigated. Based on the rate of special issuance for general aviation pilots, the FAA assumes that 10% of the commercial balloon pilot applicants would require a special issuance. For purposes of this analysis, the FAA assumes that most applicants would ultimately either receive a second-class medical certificate or be granted a special issuance and therefore does not quantify costs associated with not meeting the requirements.

However, the FAA expects some applicants who would have otherwise been able to operate as commercial balloon pilots may not meet the requirements of a second-class medical certification nor the requirements for a special issuance. Furthermore, the

opportunity cost (including the time and fees) of seeking a second-class medical certification for some pilots may outweigh their private gains from operating commercially, resulting in some pilots opting not to seek medical certification. The FAA does not have sufficient information to predict how the supply of commercial balloon pilots would change as a result of this rule.

While the FAA does not expect a significant decrease in the availability of balloon pilots, changes in supply of balloon pilots could affect prices as well. This analysis does not quantify any potential changes in consumer and producer surplus from changes in supply. If the rule effectively screens out certain individuals for disqualifying medical conditions as intended, any potential adverse effects on individual applicants should be offset by the safety gains to the public.

TABLE 10—TOTAL COSTS OF THE RULE

Year	Total cost of the rule		
	Low	Middle	High
1	\$273,983	\$889,422	\$2,208,457
2	290,390	911,656	2,236,654
3	306,815	933,907	2,264,867
4	323,269	956,201	2,293,150
5	339,741	978,515	2,321,451
6	356,232	1,000,847	2,349,770
7	372,742	1,023,197	2,378,108
8	389,270	1,045,566	2,406,464
9	405,816	1,067,953	2,434,839

TABLE 10—TOTAL COSTS OF THE RULE—Continued

Year	Total cost of the rule		
	Low	Middle	High
10	422,381	1,090,359	2,463,232
Present Value at 7%	2,380,511	6,864,816	16,294,834
Annualized at 7%	338,931	977,395	2,320,018
Present Value at 3%	2,934,807	8,396,497	19,865,182
Annualized at 3%	344,049	984,326	2,328,805

Breakeven Analysis

Given the uncertainties and limitations in the available data, the FAA conducted a breakeven analysis to determine the number of averted fatalities necessary to generate benefits equal to costs. The FAA divided the present value of total costs of the rule by the present value of a statistical life to estimate the number of fatalities needed to break even with the costs of the rule over a ten-year time horizon. Using a value of statistical life of \$11.6 million and the range of present value of costs presented in Table 10 above, the monetized benefits of this rule will break even with costs if the new medical certification requirement averts between 0.4 to 2.8 fatalities under a 7 percent discount rate and between 0.3 to 2.3 fatalities under a 3 percent discount rate.²⁵

Regulatory Alternatives

As discussed in the NPRM, the FAA considered one alternative to the proposed rule: Letter of Authorization (LOA) and Drug and Alcohol Testing.

With this alternative, the FAA would have instituted both a medical certificate requirement as well as a requirement for obtaining an LOA from the FAA and mandatory drug and alcohol testing. This alternative would have expanded the definition of an operator under § 91.147 to include balloons, which would have required the commercial balloon operators to obtain an LOA from the FAA in accordance with § 91.147 prior to conducting air tour operations, and implement a drug and alcohol testing program in accordance with 14 CFR part 120. However, as discussed elsewhere in this final rule, this alternative goes beyond the statutory mandate. Therefore, the FAA did not adopt this alternative.

B. Regulatory Flexibility Act

The Regulatory Flexibility Act (RFA) of 1980, Public Law 96–354, 94 Stat. 1164 (5 U.S.C. 601–612), as amended by the Small Business Regulatory Enforcement Fairness Act of 1996 (Pub. L. 104–121, 110 Stat. 857, Mar. 29, 1996) and the Small Business Jobs Act of 2010 (Pub. L. 111–240, 124 Stat. 2504 Sept. 27, 2010), requires Federal agencies to consider the effects of the regulatory action on small business and other small entities and to minimize any significant economic impact. The term “small entities” comprises small businesses and not-for-profit organizations that are independently owned and operated and are not dominant in their fields, and governmental jurisdictions with populations of less than 50,000.

The FAA published an Initial Regulatory Flexibility Analysis (IRFA) in the proposed rule to aid the public in commenting on the potential impacts to small entities. The FAA considered the public comments in developing the final rule and this Final Regulatory Flexibility Analysis (FRFA). A FRFA must contain the following:

- (1) A statement of the need for, and objectives of, the rule;
- (2) A statement of the significant issues raised by the public comments in response to the IRFA, a statement of the assessment of the agency of such issues, and a statement of any changes made in the proposed rule as a result of such comments;
- (3) The response of the agency to any comments filed by the Chief Counsel for Advocacy of the Small Business Administration (SBA) in response to the proposed rule, and a detailed statement of any change made to the proposed rule in the final rule as a result of the comments;
- (4) A description of and an estimate of the number of small entities to which the rule will apply or an explanation of why no such estimate is available;
- (5) A description of the projected reporting, recordkeeping, and other compliance requirements of the rule, including an estimate of the classes of

small entities which will be subject to the requirement and the type of professional skills necessary for preparation of the report or record; and

(6) A description of the steps the agency has taken to minimize the significant economic impact on small entities consistent with the stated objectives of applicable statutes, including a statement of the factual, policy, and legal reasons for selecting the alternative adopted in the final rule and why each of the other significant alternatives to the rule considered by the agency which affect the impact on small entities was rejected.

Statement of the Need for and Objectives of the Rule

This rulemaking addresses the need for additional oversight of airmen conducting balloon operations for compensation or hire by implementing the statutory mandate under the Commercial Balloon Pilot Safety Act of 2018 and NTSB Safety Recommendation A–17–034 to extend second-class medical certification requirements to operators of balloons.

The objective of the rule is to enhance safety for passengers of commercial balloon operations by requiring pilots to obtain and hold second-class medical certificates, in compliance with Section 318, to prevent potential accidents in commercial balloon operations.

Significant Issues Raised in Public Comments

The FAA received 192 comments during the public comment period. One significant issue commenters raised was the concern that the proposed rule would impose significant burdens on balloon pilots and could put some of them out of business, causing the supply of balloon pilots to shrink. The FAA assessed this concern and does not believe that the costs of the rule would cause such an undue burden. The cost estimate per pilot to obtain a second-class medical certificate is between \$160 and \$685 annually, depending on whether a special issuance would be necessary, which is the equivalent of 0.06% to 0.37% of average annual

²⁵ Departmental Guidance on Valuation of a Statistical Life in Economic Analysis <https://www.transportation.gov/office-policy/transportation-policy/revised-departmental-guidance-on-valuation-of-a-statistical-life-in-economic-analysis>.

revenues for small entities. The FAA considers this expense to be non-significant to cause such a decline in the number of balloon pilots. A more detailed analysis may be found under the Description and an Estimated Number of Small Entities Impacted section.

In addition, several commenters noted that larger balloon operations require their pilots to carry second-class medical certificates as part of insurance requirements. These balloon pilots do not have to incur additional costs as a result of the final rule. The FAA estimates about 8.8% of balloon pilots fall into this category. However, the vast majority of balloon pilots are not currently required to hold second-class medical certificates either by the FAA or insurance carriers. There was no change made to the final rule as a result of public comments.

Response to SBA Comments

The FAA received no comments from the Chief Counsel for Advocacy of the Small Business Administration.

Description and an Estimated Number of Small Entities Impacted

The final rule affects commercial balloon pilots and establishments involved in commercial balloon operations. The FAA does not maintain a database of commercial balloon operators actively operating in the United States. Using commercial sources, the FAA estimates that number to be about 356²⁶ companies. Approximately 4,870 commercial pilots hold balloon ratings, and approximately 4,940 balloons are registered with the FAA. The commercial balloon industry estimates that 100,000 to 250,000 passenger rides are conducted annually, as well as aerial advertising and other commercial activities.

FAA used the definition of small entities in the RFA for this analysis. The RFA defines small entities as small businesses, small governmental jurisdictions, or small organizations. In 5 U.S.C. § 601(3), the RFA defines “small business” to have the same meaning as “small business concern” under section 3 of the Small Business Act. The Small Business Act authorizes the Small Business Administration (SBA) to define “small business” by issuing regulations. SBA (2019) has established size standards for various types of economic activities, or industries, under the North American Industry Classification System

(NAICS).²⁷ These size standards generally define small businesses based on the number of employees or annual receipts. Note that the SBA definition of a small business applies to the parent company and all affiliates as a single entity.

To identify small entities, the FAA first identified the primary NAICS of the airline or parent company, and then used data from different sources (*e.g.*, company annual reports, Bureau of Transportation Statistics) to determine whether the parent company meets the applicable size standard. Businesses affected by this rule are classified using the 2017 North American Industry Classification System²⁸ under NAICS code 487990 “Scenic and Sightseeing Transportation, Other.” This industry comprises establishments primarily engaged in providing scenic and sightseeing transportation (except on land and water). The U.S. Small Business Administration (SBA) defines entities in this industry as “small” using an average annual revenue threshold of \$8 million.²⁹ With limited information and data on sales revenues for each of the affected commercial balloon operators, the FAA has uncertainty as to how many entities would meet the SBA’s small-entity criteria.³⁰ Furthermore, the FAA has uncertainty as to how the burden associated with the final rule would be distributed across commercial balloon companies versus individual balloon pilots employed by an operator. The FAA requested comment and data on the average annual sales revenues for the affected small businesses and to what extent the costs of obtaining a second-class medical certification would be considered an “out-of-pocket” cost incurred by commercial balloon pilots rather than a cost to the commercial balloon operator. The only information received was that the ballooning insurance providers have required commercial pilots flying balloons larger than 120,000 cubic feet to hold a second-class medical certificate. Data

²⁷ Small Business Administration (SBA). 2019. Table of Size Standards. Effective August 12, 2019. <https://www.sba.gov/document/support-table-size-standards>.

²⁸ <https://www.census.gov/naics/?input=487990&year=2017&details=487990>.

²⁹ https://www.sba.gov/sites/default/files/2019-08/SBA%20Table%20of%20Size%20Standards_Effective%20Aug%202019%2C%202019_Rev.pdf.

³⁰ Rainbow Ryders is one of the larger commercial balloon companies and are under the Small Business Administration small-entity criteria. Therefore, the FAA estimates that all of the Commercial balloon companies are a small entity. *It's Been a Year of Growth for Rainbow Ryders*, <https://www.abqjournal.com/1095655/its-been-a-growth-year-for-rainbow-ryders.html>, September 9, 2019.

indicated 427 balloon pilots have second-class medical certificates, and the FAA has made this adjustment to recompute the costs of this final rule. As previously described, the FAA estimates the cost per pilot to obtain a second-class medical certificate would be between \$160 and \$685 annually, depending on whether a special issuance would be necessary.

For purposes of this final regulatory flexibility analysis, the FAA assumes that the private sector costs of this rule (*i.e.*, the cost to obtain a second-class medical certification or special issuance) fall entirely on commercial balloon operators. In the absence of data on annual receipts specific to the commercial balloon industry, the FAA relies on the most recent data available on average revenues for all businesses, including commercial balloon operators, classified under NAICS 487990 “Scenic and Sightseeing Transportation, Other” from the 2017 Census Bureau’s Statistics of U.S. Businesses (SUSB)³¹ to inform the analysis. Note that the total number of firms identified for this industry is less than the FAA estimated number of commercial balloon operators. In this analysis, the FAA uses the SUSB data to estimate the proportion of balloon companies for each size category by annual receipts.

The table below summarizes the total number of firms, employment, and estimated annual receipts by annual receipt category for the entire industry classified under NAICS 487990 “Scenic and Sightseeing Transportation, Other” for the year 2017. Note that blanks in the table below reflect data that the Census Bureau withheld to avoid disclosing data for individual companies but are included in the higher-level totals. After adjusting the 2017 dollar values to constant 2021 dollars using the GDP deflator,³² the FAA estimates that approximately 93 percent of companies (or about 331 balloon operators extrapolating from this percentage) may be considered small entities under the SBA definition.

To compare the compliance costs of the rule to the average revenues of small entities, for each receipt size category the FAA multiplies the proportion of total employment by the annualized private sector costs of the rule and divides by the estimated annual receipts

³¹ Available at <https://www.census.gov/data/tables/2017/econ/subs/2017-annual.html>, retrieved on August 15, 2021.

³² Available at: <https://www.whitehouse.gov/omb/historical-tables/>.

²⁶ http://www.blastvalve.com/Balloon_Rides/USA/index.shtml.

in 2021 dollars.³³ Assuming that costs are proportional to employment size, which may be reasonable given that costs are driven by the number of pilots requiring a second-class medical certification, the FAA estimates that the

costs of the final rule constitutes 0.06% to 0.37% of average annual revenues for small entities. Given the currency and level of aggregation of the data available, the FAA requested comment on accuracy of these estimates and any

other information or data that would be relevant for estimating the effects of the rule on small entities but did not receive any during the comment period.

TABLE 11—NUMBER OF FIRMS, ESTABLISHMENTS, EMPLOYMENT, AND ESTIMATED RECEIPTS BY ENTERPRISE RECEIPT SIZES FOR THE UNITED STATES, NAICS 487990: 2017

[Census statistics of U.S. businesses]

Enterprise receipt size ^a	Number of firms ^b	Percentage of firms	Employment	Percentage of total employment	Estimated receipts (\$1,000)	Cost for all firms in size category (\$1,000)	Cost as a percentage of receipts
<\$100,000	53	17	48	1	2,255	9	0.37
\$100,000–499,999	119	39	192	5	29,644	37	0.11
\$500,000–999,999	47	15	237	7	32,765	45	0.13
\$1,000,000–2,499,999	43	14	365	10	63,134	70	0.10
\$2,500,000–4,999,999	18	6	323	9	65,788	62	0.09
\$5,000,000–7,499,999	6	2	106	3	29,465	20	0.06
\$7,500,000–9,999,999	5	2	213	6	41,585	41	0.09
\$10,000,000–14,999,999	4	1.3	196	5	50,270	38	0.07
\$20,000,000–24,999,999							
\$25,000,000–29,999,999	3	1.0	93	3	19,490	18	0.08
\$30,000,000–34,999,999							
\$35,000,000–39,999,999							
\$50,000,000–74,999,999							
\$100,000,000+	4	1	1,044	29	251,871	200	0.07
Total	309	100	3,611	100	762,426	691	0.08

^a Using the Gross Domestic Product (GDP) deflator, the FAA finds that \$7.49 million in 2017 dollars would be approximately \$ 8.16 million in 2021 dollars. Therefore, the FAA assumes firms with receipts of less than \$7.49 million in 2017 dollars would be considered small.

^b The FAA notes that the number of firms in NAICS 487990 is lower than FAA's estimate of the number of balloon operators. For purposes of this analysis, the SUBS data is used to estimate the percentage of small entities and the distribution of costs relative to revenues.

Description of the Recordkeeping and Other Compliance Requirements

The FAA requires that airmen hold a valid second-class medical certificate when exercising the privileges of a commercial pilot certificate in a balloon for compensation or hire. A medical certificate is not required for commercial pilots conducting flight training in a balloon. As determined by a physical examination and review of medical history, airmen must meet the applicable medical standards of part 67 in order to receive an unrestricted medical certificate. In cases where the airman's medical condition does not meet the part 67 standard, the airman may still be issued a medical certificate by authorization for special issuance or SODA when the Federal Air Surgeon had determined that the risk associated with the medical condition(s) is sufficiently mitigated.

A person obtains a medical certificate by completing an online application (FAA form 8500–8, Application for Medical Certificate) using the FAA's medical certificate application tool, MedXPress,³⁴ and undergoing a physical examination with an FAA-designated AME. An AME may defer an applicant to the FAA for further review

(which may include further examination and testing by a specialist physician) when there is information indicating the existence or potential of an adverse medical finding that may warrant further FAA medical evaluation and oversight. Second-class medical certificates held for any operations requiring a commercial pilot certificate (including the second-class medical certificates that is required for balloon operations under this final rule) expire at the end of the last day of the 12th month after the month of the date of examination shown on the medical certificate.

Alternatives Considered To Minimize Any Significant Economic Impact on Small Entities

The FAA has not identified any significant alternative that would minimize any significant economic impact on small entities which do not conflict with the statutory mandate. During the comment period, the FAA solicited comment on potential alternative approaches that could minimize the burden on small entities while still accomplishing the objectives of the proposal and did not receive any suggestions.

C. International Trade Impact Assessment

The Trade Agreements Act of 1979 (Pub. L. 96–39), as amended by the Uruguay Round Agreements Act (Pub. L. 103–465), prohibits Federal agencies from establishing standards or engaging in related activities that create unnecessary obstacles to the foreign commerce of the United States. Pursuant to these Acts, the establishment of standards is not considered an unnecessary obstacle to the foreign commerce of the United States, so long as the standard has a legitimate domestic objective, such as the protection of safety, and does not operate in a manner that excludes imports that meet this objective. The statute also requires consideration of international standards and, where appropriate, that they be the basis for U.S. standards. The FAA has assessed the potential effect of this final rule and determined that it will not create unnecessary obstacles to the foreign commerce of the United States.

The FAA has assessed the potential effect of this rule and determined that it ensures the safety of the American public and does not exclude imports that meet this objective. As a result, the

³³ For this calculation, the FAA uses the mid-estimate of \$691,486 for the total private sector costs annualized at a 7 percent discount rate.

³⁴ <https://medxpress.faa.gov/>.

FAA does not consider this rule as creating an unnecessary obstacle to foreign commerce.

D. Unfunded Mandates Assessment

The Unfunded Mandates Reform Act of 1995 (2 U.S.C. 1531–1538) governs the issuance of Federal regulations that require unfunded mandates. An unfunded mandate is a regulation that requires a State, local, or tribal government or the private sector to incur direct costs without the Federal government having first provided the funds to pay those costs. The FAA determined that the final rule will not result in the expenditure of \$165,000,000 or more by State, local, or tribal governments, in the aggregate, or the private sector, in any one year.

E. Paperwork Reduction Act

The Paperwork Reduction Act of 1995 (44 U.S.C. 3507(d)) requires that the FAA consider the impact of paperwork and other information collection burdens imposed on the public.

According to the 1995 amendments to the Paperwork Reduction Act (5 CFR

1320.8(b)(2)(vi)), an agency may not collect or sponsor the collection of information, nor may it impose an information collection requirement unless it displays a currently valid Office of Management and Budget (OMB) control number.

This final rule contains the following amendments to the existing information collection requirements previously approved under OMB Control No. 2120–0034. In the analysis below, the FAA describes the incremental changes in the number of respondents, annual burden, and monetized costs of the existing information collection requirement previously approved under OMB Control No. 2120–0034. As required by the Paperwork Reduction Act of 1995 (44 U.S.C. 3507(d)), the FAA has submitted the information collection requirements to OMB for its review.

Requirements To Hold a Second-Class Medical Certificate

The final rule requires airmen to hold a valid second-class medical certificate when exercising the privileges of a

commercial pilot certificate in a balloon for compensation or hire. To obtain a medical certificate, an airman has to complete an online application (FAA form 8500–8, Application for Medical Certificate) using the FAA's medical certificate application tool, MedXPress and undergo a physical examination with an FAA-designated Aviation Medical Examiner (AME).

In Table 12 below, the FAA shows the incremental burden of this rule to the approved information collection under OMB Control No. 2120–0034. Additional details on assumptions and calculations used in this section are presented elsewhere in the Regulatory Evaluation section of this document.

Estimates of the Hour Burden of the Collection of Information

The mid estimate of the number of applicants in the first year is 2,277.

TABLE 12—BURDEN HOURS ASSOCIATED WITH MEDXPRESS FORM 8500–8

Form No.	Number of applicants	Hours per applicant	Total hours
8500–8	2,277	1.5	3,416

Estimate of the Total Annual Cost Burden to Respondents or Record Keepers Resulting From the Collection of Information

Once the information on FAA Form 8500–8 is collected, respondents must receive a medical examination in order to be certificated to exercise commercial balloon pilot privileges. The average fee for a basic medical examination is estimated at \$150. The total cost for medical exams in the first year is as follows:

$$\$150 \times 2,277 \text{ submissions of Form 8500–8} = \$ 341,550$$

Estimates of Annualized Costs to the Federal Government

The estimated annualized cost to the Federal Government to implement the final rule is between \$133,339 and \$540,118, with a mid-estimate of \$285,910 at a 7 percent discount rate. The FAA would incur costs associated with reviewing and processing applications submitted through MedXPress. It costs about \$30 per medical certification review using the primary estimate for the number of applications in the first year, the FAA estimates a total cost of \$67,399 (=

\$29.60 per application \times 2,277) in the first year.

Currently, a MedXPress application that requires a special issuance medical certificate is deferred to the AMCD of Oklahoma City for further consideration. The FAA assumes that 10 percent of the applicants do not initially qualify for second-class medical certification and, therefore, would require special issuance. The average cost to FAA for each medical certificate special issuance review is approximately \$126.

The total annualized costs for the FAA to review, including NDR and process MedXPress applications from commercial balloon applicants and costs for the FAA to conduct Special Issuance Review for commercial balloon applicants is between \$98,855 and \$400,430, with a mid-estimate of \$211,967 at a 7 percent discount rate over ten years.

F. International Compatibility

In keeping with U.S. obligations under the Convention on International Civil Aviation, it is FAA policy to conform to International Civil Aviation Organization (ICAO) Standards and

Recommended Practices to the maximum extent practicable. The FAA has reviewed the corresponding ICAO Standards and Recommended Practices and has determined that this rule will require a minor modification to the existing differences filed in regard to medical certification for commercial balloon pilots. Currently, the U.S. has filed a difference stating that balloon pilots are not required to hold a medical certificate but are prohibited from operating during periods of medical deficiency. This statement will be updated to reflect the medical certificate requirement described in this rule.

G. Environmental Analysis

FAA Order 1050.1F identifies FAA actions that are categorically excluded from preparation of an environmental assessment or environmental impact statement under the National Environmental Policy Act in the absence of extraordinary circumstances. The FAA has determined this rulemaking action qualifies for the categorical exclusion identified in paragraph 5–6.6f for regulations and involves no extraordinary circumstances.

VI. Executive Order Determination*A. Executive Order 13132, Federalism*

The FAA has analyzed this final rule under the principles and criteria of Executive Order 13132, Federalism. The agency has determined that this action does not have a substantial direct effect on the States, or the relationship between the Federal Government and the States, or on the distribution of power and responsibilities among the various levels of government, and, therefore, does not have federalism implications.

B. Executive Order 13211, Regulations That Significantly Affect Energy Supply, Distribution, or Use

The FAA analyzed this final rule under Executive Order 13211, Actions Concerning Regulations that Significantly Affect Energy Supply, Distribution, or Use. The FAA has determined that this final rule is not a “significant energy action” under the executive order and it will not be likely to have a significant adverse effect on the supply, distribution, or use of energy.

C. Executive Order 13609, International Cooperation

Executive Order 13609, Promoting International Regulatory Cooperation, promotes international regulatory cooperation to meet shared challenges involving health, safety, labor, security, environmental, and other issues and to reduce, eliminate, or prevent unnecessary differences in regulatory requirements. The FAA has analyzed this action under the policies and agency responsibilities of Executive Order 13609, and has determined that this action reduces differences between U.S. aviation standards and those of other civil aviation authorities by bringing U.S. regulatory requirements partially into compliance with International Civil Aviation Organization (ICAO) standards for medical certification.³⁵

VII. Privacy

The information collected from FAA Form 8500–8 becomes part of the Privacy Act System of Records DOT/FAA 847, “Aviation Records on Individuals,” [DOT/FAA 847] and is provided the protection outlined in the description of the system as published in the **Federal Register**.

³⁵ The 12th edition of the Annex 1 to the Convention on International Civil Aviation, Personnel Licensing, (July 2018), specifies that a person exercising the privileges of a Free Balloon Pilot License must hold a Class 2 medical. See 2.10.1.5.

VIII. Additional Information*A. Electronic Access and Filing*

A copy of the NPRM, all comments received, this final rule, and all background material may be viewed online at <https://www.regulations.gov> using the docket number listed above. Electronic retrieval help and guidelines are available on the website. It is available 24 hours each day, 365 days each year. An electronic copy of this document may also be downloaded from the Office of the Federal Register’s website at <https://www.federalregister.gov> and the Government Publishing Office’s website at <https://www.govinfo.gov>. A copy may also be found on the FAA’s Regulations and Policies website at https://www.faa.gov/regulations_policies.

Copies may also be obtained by sending a request to the Federal Aviation Administration, Office of Rulemaking, ARM–1, 800 Independence Avenue SW, Washington, DC 20591, or by calling (202) 267–9677. Commenters must identify the docket or amendment number of this rulemaking.

All documents the FAA considered in developing this final rule, including economic analyses and technical reports, may be accessed in the electronic docket for this rulemaking.

B. Small Business Regulatory Enforcement Fairness Act

The Small Business Regulatory Enforcement Fairness Act (SBREFA) of 1996 requires the FAA to comply with small entity requests for information or advice about compliance with statutes and regulations within its jurisdiction. A small entity with questions regarding this document may contact its local FAA official, or the person listed under the **FOR FURTHER INFORMATION CONTACT** heading at the beginning of the preamble. To find out more about SBREFA on the internet, visit https://www.faa.gov/regulations_policies/rulemaking/sbre_act/.

List of Subjects*14 CFR Part 61*

Aircraft, Airmen, Alcohol abuse, Aviation safety, Drug abuse, Flight instruction, Medical certification, Recreation and recreation areas, Reporting and recordkeeping requirements, Security measures, Teachers.

14 CFR Part 68

Aircraft, Airmen, Health, Reporting and Recordkeeping requirements.

The Amendment

In consideration of the foregoing, the Federal Aviation Administration amends chapter I of title 14, Code of Federal Regulations as follows:

PART 61—CERTIFICATION: PILOTS, FLIGHT INSTRUCTORS, AND GROUND INSTRUCTORS

■ 1. The authority citation for part 61 is revised to read as follows:

Authority: 49 U.S.C. 106(f), 106(g), 40113, 44701–44703, 44707, 44709–44711, 44729, 44903, 45102–45103, 45301–45302.

■ 2. Amend § 61.3 by revising paragraphs (c)(2)(xiii) and (c)(2)(xiv), and adding paragraph (c)(2)(xv) to read as follows:

§ 61.3 Requirement for certificates, ratings, and authorizations.

* * * * *

(c) * * *

(2) * * *

(xiii) Is exercising the privileges of a student, recreational or private pilot certificate for operations conducted under the conditions and limitations set forth in § 61.113(i) and holds a U.S. driver’s license;

(xiv) Is exercising the privileges of a flight instructor certificate and acting as pilot in command or a required flightcrew member for operations conducted under the conditions and limitations set forth in § 61.113(i) and holds a U.S. driver’s license; or

(xv) Is exercising the privileges of a student pilot certificate or higher while acting as pilot in command on a special medical flight test authorized under part 67 of this chapter.

* * * * *

■ 3. Effective May 22, 2023, amend § 61.3 by revising paragraph (c)(2)(vi) to read as follows:

§ 61.3 Requirement for certificates, ratings, and authorizations.

* * * * *

(c) * * *

(2) * * *

(vi) Is holding a pilot certificate with a balloon class rating and that person—

(A) Is exercising the privileges of a private pilot certificate in a balloon; or

(B) Is providing flight training in a balloon in accordance with § 61.133(a)(2)(ii);

* * * * *

■ 4. Amend § 61.23 by:

■ a. Revising paragraphs (b)(8) and (b)(9)(ii);

■ b. Adding paragraph (b)(10); and

■ c. Revising paragraphs (c)(3)(i)(C), (c)(3)(i)(D), and (c)(3)(i)(E).

The revisions and additions read as follows:

§ 61.23 Medical certificates: Requirement and duration.

* * *

(b) * * *

(8) When taking a practical test or a proficiency check for a certificate, rating, authorization or operating privilege conducted in a glider, balloon, flight simulator, or flight training device;

(9) * * *

(ii) The flight conducted is a domestic flight operation within U.S. airspace; or

(10) When exercising the privileges of a student pilot certificate or higher while acting as pilot in command on a special medical flight test authorized under part 67 of this chapter.

(c) * * *

(3) * * *

(i) * * *

(C) Complete the medical education course set forth in § 68.3 of this chapter during the 24 calendar months before acting as pilot in command or serving as a required flightcrew member in an operation conducted under § 61.113(i) and retain a certification of course completion in accordance with § 68.3(b)(1) of this chapter;

(D) Receive a comprehensive medical examination from a State-licensed physician during the 48 months before

acting as pilot in command or serving as a required flightcrew member of an operation conducted under § 61.113(i) and that medical examination is conducted in accordance with the requirements in part 68 of this chapter; and

(E) If the individual has been diagnosed with any medical condition that may impact the ability of the individual to fly, be under the care and treatment of a State-licensed physician when acting as pilot in command or serving as a required flightcrew member of an operation conducted under § 61.113(i).

* * *

■ 5. Effective May 22, 2023, amend § 61.23 by:

■ a. Revising paragraphs (a)(2)(i) and (a)(2)(ii);

■ b. Adding paragraph (a)(2)(iii);

■ c. Revising paragraph (b)(3);

■ d. Redesignating paragraphs (b)(4) through (b)(10) as paragraphs (b)(6) through (b)(12); and

■ e. Adding new paragraphs (b)(4) and (b)(5);

■ f. Revising paragraphs (d)(1)(iii) and (d)(2)(i).

The revisions and additions read as follows:

§ 61.23 Medical certificates: Requirement and duration.

(a) * * *

(2) * * *

(i) Second-in-command privileges of an airline transport pilot certificate in part 121 of this chapter (other than operations specified in paragraph (a)(1)(ii) of this section);

(ii) Privileges of a commercial pilot certificate in an aircraft other than a balloon or glider; or

(iii) Except as provided in paragraph (b)(5) of this section, privileges of a commercial pilot certificate with a balloon class rating for compensation or hire; or

(b) * * *

(3) When exercising the privileges of a pilot certificate with a glider category rating in a glider;

(4) When exercising the privileges of a private pilot certificate with a balloon class rating in a balloon;

(5) When exercising the privileges of a commercial pilot certificate with a balloon class rating in a balloon if the person is providing flight training in accordance with § 61.133(a)(2)(ii);

* * *

(d) * * *

If you hold	And on the date of examination for your most recent medical certificate you were	And you are conducting an operation requiring	Then your medical certificate expires, for that operation, at the end of the last day of the
(1) * * *			
	(iii) Any age	a commercial pilot certificate (other than a commercial pilot certificate with a balloon rating when conducting flight training), a flight engineer certificate, or an air traffic control tower operator certificate.	12th month after the month of the date of examination shown on the medical certificate.
	*	*	*
(2) * * *			
	(i) Any age	an airline transport pilot certificate for second-in-command privileges (other than the operations specified in paragraph (d)(1) of this section), a commercial pilot certificate (other than a commercial pilot certificate with a balloon rating when conducting flight training), a flight engineer certificate, or an air traffic control tower operator certificate.	12th month after the month of the date of examination shown on the medical certificate.
	*	*	*

■ 6. Amend § 61.113 by revising the introductory text of paragraph (i) to read as follows:

§ 61.113 Private pilot privileges and limitations: Pilot in command.

* * *

(i) A private pilot may act as pilot in command or serve as a required flightcrew member of an aircraft without holding a medical certificate issued under part 67 of this chapter provided the pilot holds a valid U.S. driver's license, meets the requirements of

§ 61.23(c)(3), and complies with this section and all of the following conditions and limitations:

* * *

PART 68—REQUIREMENTS FOR OPERATING CERTAIN SMALL AIRCRAFT WITHOUT A MEDICAL CERTIFICATE

■ 7. The authority citation for part 68 continues to read as follows:

Authority: 49 U.S.C. 106(f), 44701–44703.

■ 8. Amend § 68.3 by revising the introductory text of paragraph (a) and the introductory text of paragraph (b) to read as follows:

§ 68.3 Medical education course requirements.

(a) The medical education course required to act as pilot in command or serve as a required flightcrew member in an operation under § 61.113(i) of this chapter must—

* * * * *

(b) Upon successful completion of the medical education course, the following items must be electronically provided to the individual seeking to act as pilot in command or serve as a required flightcrew member under the conditions and limitations of § 61.113(i) of this chapter and transmitted to the FAA—

* * * * *

■ 9. Amend § 68.9 by revising the introductory text of paragraph (a) to read as follows:

§ 68.9 Special Issuance process.

(a) *General.* An individual who has met the qualifications to operate an aircraft under § 61.113(i) of this chapter and is seeking to act as a pilot in command or serve as a required flightcrew member under that section must have completed the process for obtaining an Authorization for Special Issuance of a Medical Certificate for each of the following:

* * * * *

Issued in Washington, DC, under authority provided by 49 U.S.C. 106(f), 44701, 44702, and 44703 on or about November 16, 2022.

Billy Nolen,

Acting Administrator.

[FR Doc. 2022–25288 Filed 11–21–22; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 71

[Docket No. FAA–2022–1209; Airspace Docket No. 22–AWA–5]

RIN 2120–AA66

Amendment of Class C Airspace; Evansville, IN

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule.

SUMMARY: This action amends the Evansville Regional Airport, IN, Class C airspace description to update the airport reference point (ARP) geographic coordinates for the Evansville Regional Airport and the Skylane Airport to match the FAA’s National Airspace System Resource (NASR) database information. Additionally, this action makes technical amendments to the airspace description header information by changing the title of the airspace area and adding the Pocket City, IN (PXV), VHF Omnidirectional Range and Tactical Air Navigation (VORTAC) navigational aid. Finally this action amends the airspace description by correcting the Airport/Facility Directory reference. This action does not change the boundaries, altitudes, or operating requirements of the Class C airspace area.

DATES: Effective date 0901 UTC, February 23, 2023. The Director of the Federal Register approves this incorporation by reference action under 1 CFR part 51, subject to the annual revision of FAA Order 7400.11 and publication of conforming amendments.

ADDRESSES: FAA Order 7400.11G, Airspace Designations and Reporting Points, and subsequent amendments can be viewed online at www.faa.gov/air-traffic/publications/. For further information, you can contact the Rules and Regulations Group, Federal Aviation Administration, 800 Independence Avenue SW, Washington, DC 20591; telephone: (202) 267–8783.

FOR FURTHER INFORMATION CONTACT: Colby Abbott, Rules and Regulations Group, Office of Policy, Federal Aviation Administration, 800 Independence Avenue SW, Washington, DC 20591; telephone: (202) 267–8783.

SUPPLEMENTARY INFORMATION:

Authority for This Rulemaking

The FAA’s authority to issue rules regarding aviation safety is found in Title 49 of the United States Code.

Subtitle I, Section 106 describes the authority of the FAA Administrator. Subtitle VII, Aviation Programs, describes in more detail the scope of the agency’s authority. This rulemaking is promulgated under the authority described in Subtitle VII, Part A, Subpart I, Section 40103. Under that section, the FAA is charged with prescribing regulations to assign the use of the airspace necessary to ensure the safety of aircraft and the efficient use of airspace. This regulation is within the scope of that authority as it updates the listed airports ARP geographic coordinates information, amends the airspace description header information by changing the airspace title and adding the Pocket City VORTAC. Finally, this action corrects the airspace description by updating the Airport/Facility Directory reference.

History

Class C airspace areas are designed to improve air safety by reducing the risk of midair collisions in high volume airport terminal areas and to enhance the management of air traffic operations in that area. During a recent inquiry regarding the Evansville Regional Airport, IN, Class C airspace description and the surface area cutout for the Skylane Airport, the FAA identified that the Evansville Regional Airport and Skylane Airport ARP geographic coordinates were incorrect. This action updates the ARP geographic coordinates for both airports listed in the airspace description to coincide with the FAA’s NASR database information. After reviewing the existing airspace description, this action also makes technical amendments to the airspace description header information by changing the title of the Class C airspace area to reflect city and state instead of the airport name the airspace is designated around and by adding the Pocket City, IN (PXV), VORTAC since it is used to define the surface area cutout for the Skylane Airport. Further, a technical amendment to the airspace description corrects the Airport/Facility Directory reference. There are no changes to the boundaries, altitudes, or air traffic control services resulting from this action.

Class C airspace areas are published in paragraph 4000 of FAA Order 7400.11G, dated August 19, 2022, and effective September 15, 2022, which is incorporated by reference in 14 CFR 71.1. The Class C airspace listed in this document will be published subsequently in FAA Order JO 7400.11.

Availability and Summary of Documents for Incorporation by Reference

This document amends FAA Order 7400.11G, Airspace Designations and Reporting Points, dated August 19, 2022, and effective September 15, 2022. FAA Order 7400.11G is publicly available as listed in the **ADDRESSES** section of this document. FAA Order 7400.11G lists Class A, B, C, D, and E airspace areas, air traffic service routes, and reporting points.

The Rule

This action amends 14 CFR part 71 by amending the Evansville Regional Airport, IN, Class C airspace description to update the Evansville Regional Airport and Skylane Airport ARP geographic coordinates contained in the airspace description. The ARP geographic coordinates for the Evansville Regional Airport are changed from “lat. 38°02′17″ N, long. 87°31′50″ W.” to “lat. 38°02′27″ N, long. 87°31′43″ W.” and for the Skylane Airport are changed from “lat. 38°01′00″ N, long. 87°35′30″ W.” to “lat. 38°00′43″ N, long. 87°35′42″ W.”. These ARP geographic coordinates changes are made to coincide with the FAA’s NASR database information. Additionally, this action makes technical amendments to the airspace description header by changing the airspace title from the “Evansville Regional Airport, IN” to “Evansville, IN” and by adding the Pocket City, IN (PXV), VORTAC that is used to define the Class C surface area cutout. Finally, this action makes a technical amendment to the airspace description by correcting the “Airport/Facility Directory” reference to the “Chart Supplement”. These technical amendments are made to comply with airspace legal description guidance contained in FAA Order JO 7400.2.

This action does not affect the boundaries, altitudes, or operating requirements of the airspace. Therefore, notice and public procedure under 5 U.S.C. 553(b) is unnecessary.

FAA Order 7400.11, Airspace Designations and Reporting Points, is published yearly and effective on September 15.

Regulatory Notices and Analyses

The FAA has determined that this regulation only involves an established body of technical regulations for which frequent and routine amendments are

necessary to keep them operationally current. It, therefore: (1) is not a “significant regulatory action” under Executive Order 12866; (2) is not a “significant rule” under Department of Transportation (DOT) Regulatory Policies and Procedures (44 FR 11034; February 26, 1979); and (3) does not warrant preparation of a regulatory evaluation as the anticipated impact is so minimal. Since this is a routine matter that only affects air traffic procedures and air navigation, it is certified that this rule, when promulgated, does not have a significant economic impact on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

Environmental Review

The FAA has determined that this action making technical amendments to the Evansville, IN, Class C airspace description qualifies for categorical exclusion under the National Environmental Policy Act (42 U.S.C. 4321 *et seq.*) and its implementing regulations at 40 CFR part 1500, and in accordance with FAA Order 1050.1F, Environmental Impacts: Policies and Procedures, paragraph 5–6.5a, which categorically excludes from full environmental impact review rulemaking actions that designate or modify classes of airspace areas, airways, routes, and reporting points. Since this action does not change the boundaries, altitudes, or operating requirements of the Class C airspace area, and only amends the legal description to contain the current Evansville Regional Airport and Skylane Airport ARP geographic coordinates, this airspace action is not expected to result in any potentially significant environmental impacts. In accordance with FAA Order 1050.1F, paragraph 5–2 regarding Extraordinary Circumstances, this action has been reviewed for factors and circumstances in which a normally categorically excluded action may have a significant environmental impact requiring further analysis. Accordingly, the FAA has determined that no extraordinary circumstances exist that warrant preparation of an environmental assessment or environmental impact study.

List of Subjects in 14 CFR Part 71

Airspace, Incorporation by reference, Navigation (air).

The Amendment

In consideration of the foregoing, the Federal Aviation Administration amends 14 CFR part 71 as follows:

PART 71—DESIGNATION OF CLASS A, B, C, D, AND E AIRSPACE AREAS; AIR TRAFFIC SERVICE ROUTES; AND REPORTING POINTS

■ 1. The authority citation for 14 CFR part 71 continues to read as follows:

Authority: 49 U.S.C. 106(f), 106(g), 40103, 40113, 40120; E.O. 10854, 24 FR 9565, 3 CFR, 1959–1963 Comp., p.389.

§ 71.1 [Amended]

■ 2. The incorporation by reference in 14 CFR 71.1 of FAA Order JO 7400.11G, Airspace Designations and Reporting Points, dated August 19, 2022, effective September 15, 2022, is amended as follows:

Paragraph 4000 Class C Airspace.

* * * * *

AGL IN C Evansville, IN [Amended]

Evansville Regional Airport, IN

(Lat. 38°02′27″ N, long. 087°31′43″ W)

Skylane Airport, IN

(Lat. 38°00′43″ N, long. 087°35′42″ W)

Pocket City, IN (PXV), VORTAC

(Lat. 37°55′42″ N, long. 087°45′45″ W)

That airspace extending upward from the surface to and including 4,500 feet MSL within a 5-mile radius of the Evansville Regional Airport, excluding that airspace extending upward from the surface to 1,600 feet MSL beginning where the Pocket City VORTAC 057° radial crosses the 5-mile ring, thence northeast via the Pocket City VORTAC 057° radial to intercept a 1¼-mile radius of the Skylane Airport, thence counterclockwise via the 1¼-mile radius to the 360° bearing from the Skylane Airport, thence due west to the 5-mile ring; and that airspace extending upward from 1,600 feet MSL to and including 4,500 feet MSL within a 10-mile radius of the Evansville Regional Airport. This Class C airspace area is effective during the specific days and hours of operation of the Evansville Tower and Approach Control Facility as established in advance by a Notice to Airmen. The effective dates and times will thereafter be continuously published in the Chart Supplement.

Issued in Washington, DC, on November 16, 2022.

Scott M. Rosenbloom,

Manager, Airspace Rules and Regulations.

[FR Doc. 2022–25388 Filed 11–21–22; 8:45 am]

BILLING CODE 4910–13–P

NATIONAL AERONAUTICS AND SPACE ADMINISTRATION**14 CFR Part 1212**

[Document Number NASA–22–072; Docket Number–NASA–2022–0004]

RIN 2700–AE66

Social Security Number Fraud Prevention Act of 2017 Implementation**AGENCY:** National Aeronautics and Space Administration.**ACTION:** Final rule.

SUMMARY: The National Aeronautics and Space Administration (NASA) is finalizing amendments to its regulations under the Privacy Act. The revisions clarify and update procedural requirements on documents the Agency sends by mail which include Social Security numbers (SSNs). These revisions implement the Social Security Number Fraud Prevention Act of 2017 restricting the inclusion of SSNs on documents sent by mail by the Federal Government.

DATES: Effective December 22, 2022.**FOR FURTHER INFORMATION CONTACT:**

Stayce Hoult, Office of the Chief Information Officer, 256–544–7705.

SUPPLEMENTARY INFORMATION:

Authority and Background: The Social Security Number Fraud Prevention Act of 2017 (the Act) (Pub. L. 115–59; 42 U.S.C. 405 note), restricts Federal agencies from including individuals' SSNs on documents sent by mail, unless the head of the agency determines that the inclusion of the SSN on the document is necessary (section 2(a) of the Act). The Act requires agency heads to issue regulations specifying the circumstances under which inclusion of an SSN on a document sent by mail is necessary. These regulations, which must be issued no later than five years after the date of enactment, shall include instructions for the partial redaction of SSNs where feasible, and shall require that SSNs not be visible on the outside of any package sent by mail (section 2(b) of the Act).

Discussion of Public Comments

Received: NASA published a proposed rule in the **Federal Register** at 87 FR 46908 on August 1, 2022, to amend to its regulations at 14 CFR part 1212, subpart 1212.6. The Agency received one comment from an individual that expressed the importance of keeping SSNs safe to prevent fraud, one comment from an individual that expressed the importance of continuously updating and clarifying all revisions pertaining to SSNs because citizens value and expect privacy, and

one comment from an individual who provided information about Social Security income that is not related to this rule. As no significant issues or questions were raised by the commenters, NASA is issuing this final rule with no changes from the version proposed in August.

Regulatory Analysis**Executive Order 12866, Regulatory Planning and Review, and Executive Order 13563, Improving Regulation and Regulatory Review**

Executive Orders 12866 and 13563 direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). Executive Order 13563 emphasizes the importance of quantifying both costs and benefits of reducing costs, harmonizing rules, and promoting flexibility. This final rule is not a significant regulatory action under section 3(f) of Executive Order 12866 and was not reviewed by the Office of Management and Budget.

Review Under the Regulatory Flexibility Act

The Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*) requires an agency to prepare an initial regulatory flexibility analysis to be published at the time the final rule is published. This requirement does not apply if the agency “certifies that the rule will not, if promulgated, have a significant economic impact on a substantial number of small entities” (5 U.S.C. 605(b)). This final rule does not have any economic impact on small entities.

Review Under the Paperwork Reduction Act

This final rule does not contain any information collection requirements subject to the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*).

Review Under Executive Order of 13132

Executive Order 13132, “Federalism,” 64 FR 43255 (August 4, 1999), requires regulations be reviewed for federalism effects on the institutional interest of states and local governments, and, if the effects are sufficiently substantial, preparation of the Federal assessment is required to assist senior policy makers. The amendments will not have any direct effects on state and local governments within the meaning of the

Executive order. Therefore, no federalism assessment is required.

List of Subjects in 14 CFR Part 1212

Privacy, Privacy Act.

For reasons discussed in the preamble, NASA amends 14 CFR part 1212 as follows:

PART 1212—PRIVACY ACT—NASA REGULATIONS

■ 1. The authority citation for part 1212 is revised to read as follows:

Authority: 51 U.S.C. 20101 *et seq.*; 5 U.S.C. 552a; Pub. L. 115–59, 131 Stat. 1152 (42 U.S.C. 405 note).

■ 2. In § 1212.604, add paragraph (c) to read as follows:

§ 1212.604 Social security numbers.

* * * * *

(c) When sending physical mail, NASA will adhere to the following:

(1) Social Security account numbers shall not be visible on the outside of any package sent by mail.

(2) A document sent by mail may only include the Social Security account number of an individual if it is determined by the Administrator that the inclusion of a Social Security account number is necessary.

(3) The inclusion of a Social Security account number of an individual on a document sent by mail is necessary when—

(i) Required by law; or
(ii) Necessary to identify a specific individual and no adequate substitute is available.

(4) Social Security account numbers must be partially redacted in documents sent by mail whenever feasible.

Nanette Smith,*Team Lead, NASA Directives and Regulations.*

[FR Doc. 2022–25239 Filed 11–21–22; 8:45 am]

BILLING CODE P**DEPARTMENT OF COMMERCE****Census Bureau****15 CFR Part 90**

[Docket Number: 221116–0242]

RIN 0607–AA57

Resumption of the Population Estimates Challenge Program**AGENCY:** Census Bureau, Department of Commerce.**ACTION:** Final rule.

SUMMARY: The Bureau of the Census (Census Bureau) is resuming the

Population Estimates Challenge Program to provide eligible governmental units the opportunity to file requests for the review of population estimates for 2021 and subsequent years in forthcoming estimates series, beginning with the Vintage 2022 series that is scheduled to be published in 2023. This document lifts the stay of the Population Estimates Challenge Program regulations. This document does not implement revisions to the program or its requirements. The Census Bureau has published a proposed rule elsewhere in this issue of the **Federal Register** announcing the program's current requirements and soliciting comments about how the program might be improved.

DATES: Effective on November 22, 2022.

FOR FURTHER INFORMATION CONTACT:

Requests for additional information should be directed to Amel Toukabri, Chief, Local Government Estimates and Migration Processing Branch, 301-763-2461, and POP.Challenge@census.gov.

SUPPLEMENTARY INFORMATION: The Census Bureau typically prepares, in most years between decennial censuses, statistical estimates of the number of people residing in states and their governmental units. Under 15 CFR part 90, "Procedure for Challenging Population Estimates," the Census Bureau generally provides general-purpose governmental units the opportunity to seek a review of these estimates by providing additional data to the Census Bureau's Population Estimates Program as evidence relating to the accuracy of the estimates. In most years, a general-purpose governmental unit may file a challenge to its population estimate any time up to 90 days after the release of the estimate by the Census Bureau on its website. The Census Bureau, upon receipt of appropriate documentation to support the challenge, will attempt to resolve the discrepancy with the governmental unit in a timely manner.

With this publication, the Census Bureau provides notice that it is now resuming the Population Estimates Challenge Program to provide eligible governmental units the opportunity to challenge population estimates for 2021 and subsequent years in forthcoming estimates series, beginning with the Vintage 2022 series that is scheduled to be published in 2023.

Previously, the Census Bureau published a final rule on January 9, 2020, in the **Federal Register** (85 FR 1100) to announce that it would temporarily suspend the Population Estimates Challenge Program to accommodate the taking of the 2020 Census. This suspension ensured that

the Bureau could allocate sufficient resources to conduct and complete the 2020 decennial census, including time for the Census Bureau's Population Division staff to effectively review and evaluate the 2020 Census results, and to assist with other important post-Census activities, including the development of the 2020 Demographic Analysis estimates of net coverage error and expediting the dissemination of the Vintage 2020 estimates products for use as a benchmark in 2020 Census evaluations.

The Census Bureau has previously suspended the Population Estimates Challenge Program around the time of other censuses, and the program is typically resumed when staff assigned to decennial census-related work complete those assignments and become available to reinstate and support the operation of the Population Estimates Challenge Program. For example, the Population Estimates Challenge Program was suspended in 2010 in support of work pertaining to the 2010 Census and then resumed in 2013.¹

The Census Bureau had planned to resume the Population Estimates Challenge Program in 2022; however, those efforts were delayed as a result of significant and unexpected changes to the operational schedule for the 2020 Census, which were primarily caused by the effects of the COVID-19 pandemic and related mitigation measures.² Most notably, 2020 Census field operations were interrupted and delayed due to lockdown orders and health concerns which prevented data collection activities from proceeding on their original schedule. For example, the Nonresponse Followup Operation was originally scheduled for May 13, 2020, to July 31, 2020, but the actual dates for the operation were July 16, 2020, to October 15, 2020.

The Population Estimates Program depends on the decennial census data to serve as the starting point (or estimates base) for each new decade of annual population estimates. The schedule changes described above translated into significant and unexpected delays for processing of the 2020 Census data and the subsequent availability of data files required to research and develop the April 1, 2020 estimates base for the 2021 estimates series known as "Vintage 2021." These files only became available for use by the Population

Estimates Program on June 24, 2021, instead of the originally projected date of January 25, 2021. The resulting work leveraging these files to develop population estimates for subcounty geographies was completed on April 7, 2022, instead of the originally projected completion in early fall 2021. The methodology that is used to create the estimates informs what components of the estimates are subject to challenge. As a result, the supporting materials for the Population Estimates Challenge Program, such as the Review Guide for the Population Estimates Challenge Program, could not be finalized until the method to develop the estimates of population for subcounty geographies had been completed to ensure that the materials made available feature current methodologies and input data requirements. Once it became clear that the amount of time remaining to reinstate the Population Estimates Challenge Program for the Vintage 2021 estimates series was insufficient, the timeline for resuming the program was updated on the Census Bureau's website, in February 2022.³

The Census Bureau will resume accepting challenges to the population estimates as of November 22, 2022. At that time, states, counties, and other units of general-purpose government may initiate challenges to population estimates under the procedures set forth in 15 CFR part 90. The Census Bureau will accept challenges to the estimates for 2021 and subsequent years in forthcoming estimates series, beginning with the Vintage 2022 series that is scheduled to be published in March and May of 2023. Challenges to previous estimates series will not be accepted. See 15 CFR 90.6(a) ("A request for a challenge to a population estimate may be filed any time up to 90 days after the release of the estimate by the Census Bureau."). Although the Census Bureau has the discretion to accept untimely requests in certain circumstances, see *id.* § 90.6(b), this is not an appropriate circumstance to exercise such discretion, given the need to prioritize the agency's limited resources to prepare the forthcoming 2022 estimates, and to ensure that sufficient resources and program materials are available to support the operation of the Challenge Program and the evaluation of future challenges received.

Classification

Executive Order 12866: It has been determined that this rule is not significant for purposes of E.O. 12866.

¹ Resumption of the Population Estimates Program, 78 FR 255 (January 3, 2013) (to be effective on February 4, 2013). <https://www.federalregister.gov/d/2012-31598>.

² <https://www.census.gov/programs-surveys/decennial-census/decade/2020/planning-management/operational-adjustments.html>.

³ <https://www.census.gov/programs-surveys/popest/about/challenge-program.html>.

Executive Order 13132: It has been determined that this rule does not contain policies with federalism implications as that term is defined in E.O. 13132.

Administrative Procedure Act: The provisions of the Administrative Procedure Act (APA) requiring prior notice and opportunity for public comment are inapplicable under 5 U.S.C. 553(b)(B) because prior notice and opportunity for public comment is impracticable, unnecessary, and contrary to the public interest, given the agency's desire and ability to restart this program after an extended period of suspension to accommodate the decennial census and COVID-19-related delays. The Population Estimates Challenge Program is routinely suspended during decennial census operations in order to ensure that resources within the Population Division are allocated toward reviewing and evaluating the decennial census results. This rule only resumes the suspended program. This rule does not implement revisions to the program or its requirements. Furthermore, there is good cause to waive the thirty-day delay in effective date pursuant to 5 U.S.C. 553(d)(3), as this rule does not burden any regulated entity, including state and local governments such as county, city, town, or village. Moreover, allowing an additional thirty days before challenges is not practicable since entities have expected the return of the Population Estimates Challenge Program.

Regulatory Flexibility Act:

Because a notice of proposed rulemaking and an opportunity for public comment are not required for this rule by 5 U.S.C. 553, or by any other law, the analytical requirements of the Regulatory Flexibility Act, 5 U.S.C. 601 *et seq.*, are not applicable. Accordingly, no regulatory flexibility analysis is required and none has been prepared.

Robert L. Santos, Director, Census Bureau, approved the publication of this rule in the **Federal Register**.

List of Subjects in 15 CFR Part 90

Administrative practice and procedure, Census data, State and local governments.

PART 90—PROCEDURE FOR CHALLENGING POPULATION ESTIMATES

■ For the reason stated in the preamble, and under the authority of 13 U.S.C. 4 and 181, the stay of 15 CFR part 90 is lifted effective November 22, 2022.

Dated: November 17, 2022.

Shannon Wink,

*Program Analyst, Policy Coordination Office,
U.S. Census Bureau.*

[FR Doc. 2022-25413 Filed 11-21-22; 8:45 am]

BILLING CODE 3510-07-P

CONSUMER PRODUCT SAFETY COMMISSION

16 CFR Part 1460

[Docket No. CPSC-2015-0006]

Children's Gasoline Burn Prevention Act Regulation

AGENCY: Consumer Product Safety Commission.

ACTION: Direct final rule.

SUMMARY: The Children's Gasoline Burn Prevention Act (CGBPA or the Act) mandated, as a consumer product safety rule, the child-resistance requirements for closures on portable gasoline containers published in the voluntary standard, ASTM F2517-05. ASTM F2517 was revised in 2015 and 2017, and the U.S. Consumer Product Safety Commission (CPSC) allowed those revisions to become mandatory pursuant to the Act. On September 1, 2022, the Commission received notice that ASTM F2517 has been revised again. In this direct final rule, the Commission evaluates the revised ASTM F2517-22e1 standard and finds that the revisions carry out the purposes of the CGBPA. Accordingly, pursuant to the Act, the 2022 revisions to the child-resistance requirements of ASTM F2517 will be incorporated into the mandatory standard for closures on portable gasoline containers. This direct final rule updates the Commission's regulation to reflect that the requirements for closures on portable gasoline containers must meet the requirements in ASTM F2517-22e1.

DATES: The rule is effective on December 22, 2022, unless CPSC receives a significant adverse comment by December 7, 2022. If CPSC receives such a comment, it will publish a notice in the **Federal Register**, withdrawing this direct final rule before its effective date. The incorporation by reference of the publication listed in this rule is approved by the Director of the Federal Register as of December 22, 2022.

ADDRESSES: You can submit comments, identified by Docket No. CPSC-2015-0006, by any of the following methods:

Electronic Submissions: Submit electronic comments to the Federal eRulemaking Portal at: www.regulations.gov. Follow the

instructions for submitting comments. Do not submit through this website: confidential business information, trade secret information, or other sensitive or protected information that you do not want to be available to the public. CPSC typically does not accept comments submitted by electronic mail (email), except as described below.

Mail/hand delivery/courier/ confidential Written Submissions: CPSC encourages you to submit electronic comments by using the Federal eRulemaking Portal. You may, however, submit comments by mail, hand delivery, or courier to: Office of the Secretary, Consumer Product Safety Commission, 4330 East West Highway, Bethesda, MD 20814; telephone: (301) 504-7479.

Instructions: All submissions must include the agency name and docket number. CPSC may post all comments without change, including any personal identifiers, contact information, or other personal information provided, to: www.regulations.gov. If you wish to submit confidential business information, trade secret information, or other sensitive or protected information that you do not want to be available to the public, you may submit such comments by mail, hand delivery, or courier, or you may email them to: cpsc-os@cpsc.gov.

Docket: For access to the docket to read background documents or comments received, go to: www.regulations.gov, and insert the docket number, CPSC-2015-0006, into the "Search" box, and follow the prompts.

FOR FURTHER INFORMATION CONTACT: Julio A. Alvarado, Office of Compliance and Field Operations, Consumer Product Safety Commission, 4330 East West Highway, Bethesda, MD 20814-4408; telephone (301) 504-7418; jalvarado@cpsc.gov.

SUPPLEMENTARY INFORMATION:

A. Background

The CGBPA was enacted on July 17, 2008. Section 2(b) of the Act requires that each portable gasoline container manufactured on or after January 17, 2009, for sale in the United States, "shall conform to the child-resistance requirements for closures on portable gasoline containers specified in the standard ASTM F2715-05," *Standard Specification for Determination of Child Resistance of Portable Fuel Containers for Consumer Use*. CGBPA, Public Law 110-278; 122 Stat. 2602, Sec. 2(b) (July 17, 2008), codified as a note to 15 U.S.C. 2056. ASTM F2715-05 established requirements for determining the child

resistance of gasoline containers and other types of portable fuel containers, to mitigate hazards associated with children under age 5 accessing gasoline. Section 2(a) of the Act states that the provision of section 2(b) shall be considered to be a consumer product safety rule issued by the CPSC under section 9 of the Consumer Product Safety Act, 15 U.S.C. 2058.

Under section 2(d) of the Act, ASTM must notify the Commission of any revision to the child-resistance requirements of ASTM F2517–05. Once ASTM notifies the CPSC, the revisions will be incorporated by operation of law into the consumer product safety rule unless, within 60 days of such notice, the Commission determines that the revisions do not carry out the purposes of section 2(b) of the CGBPA, and so notifies ASTM.

In February 2015, ASTM notified CPSC that it had revised ASTM F2517–05 with the publication of ASTM F2517–15. The Commission determined that the revisions in ASTM F2517–15 carried out the purposes of section 2(b) of the CGBPA, and those revisions were incorporated into the mandatory standard in April 2015. The Commission published a direct final rule (DFR) codifying the incorporation by reference of ASTM F2517–15 at 16 CFR part 1460. 80 FR 16961 (Mar. 31, 2015). In November 2017, ASTM again notified the Commission that it had revised ASTM F2517. The Commission allowed ASTM F2517–17 to be incorporated into the mandatory standard and published a DFR updating the incorporation by reference in the CFR. 82 FR 58728 (Dec. 14, 2017).

On September 1, 2022, ASTM notified CPSC of another revision, ASTM F2517–22e1. Unless the Commission determines that the revised standard does not carry out the purposes of section 2(b) of the CGBPA and notifies ASTM of such a determination by October 31, 2022, the revision will be incorporated into the mandatory consumer product safety standard by operation of law.

As set forth in section B. Description of the Rule in this preamble, the Commission has determined that the revisions made to ASTM F2517 carry out the purposes of section 2(b) of the CGBPA. Accordingly, by operation of law, ASTM F2517–22e1 will be incorporated into mandatory standard, and this direct final rule updates 16 CFR part 1460 to incorporate by reference ASTM F2517–22e1.¹

B. Description of the Rule

ASTM F2517–22e1, which was published in August 2022, is an editorially corrected version of ASTM F2517–22, which was published in July 2022. Compared to ASTM F2517–17, ASTM F2517–22e1 contains substantive revisions as well as editorial, non-substantive revisions. After reviewing the changes to the child-resistance requirements in sections 2 through 7 of F2517–22e1, the Commission concludes that these revisions carry out the purposes of section 2(b) of the Act.

The revisions in ASTM F2517–22e1 update the standard to reflect current gasoline container designs, remove ambiguities in the child test requirements, creates an adult test that reflects usage patterns and applies requirements to aftermarket products such as pour spouts which make it more likely that containers will not be left unsecured and accessible to children. The Commission concludes that these changes carry out the purposes of section 2(b) of the Act by improving the portable gasoline container standard, compared to the requirements of ASTM F2517–05. Below is a discussion of ASTM F2517–05, subsequent revisions to the standard, and the substantive and non-substantive changes made to ASTM F2517–22e1. These changes, and the background of the voluntary standard, are described in more detail in the CPSC staff's briefing memorandum.²

1. Requirements in ASTM F2517–05

The Act made the child-resistance requirements in ASTM F2517–05 for closures on portable gasoline containers a mandatory consumer product safety standard. Section 2(d) of the Act makes this 2005 version of the standard a benchmark for assessing revisions to the standard. ASTM F2517–05 required that container closures have adequate resistance to opening by children between 42 months (3 years and 6 months) and 51 months of age (4 years and 3 months). ASTM 2517–05 also required performance testing to demonstrate that containers could be opened by older adults.

The child and older adult testing requirements in ASTM F2517–05 were based on the Poison Prevention Packaging Act (PPPA), 15 U.S.C. 1471–77. In 2005, gasoline containers had one opening to fill and pour from the container. To store the container, a consumer would screw on a threaded

cap, typically using a ratchet mechanism similar to child-resistant medicine bottles. To fill the gasoline container, or attach a nozzle to pour from the container, one would use force and squeeze to defeat the ratchet. The nozzles used in 2005 generally did not contain any closures or child-resistance features. Containers also had a second small opening to vent the container. ASTM F2517–05 did not require a child-resistant closure for the vent opening. Gasoline vapors would escape the gasoline container through the vent opening.

ASTM F2517–05 included a requirement for a child test program using a panel of children. The child test required the container to pass a two-part test. First, the tester would ask a pair of children to open the container and give them 5 minutes to open it. If a child opened a container, the test result for that child was marked a failure. The second part of the test was for children who did not open their containers in the first part of the test. The tester would visually demonstrate opening the container, ask the children to open it, and then give the children 5 minutes to open the container. If a child opened a container, the test result was marked a failure. If a child did not open a container, the result was marked a pass.

The older adult test program used 100 adults between 50 and 70 years old, consisting of at least 70 percent women. The older adult test had two parts. First, the tester would ask an older adult to open all the caps on the container according to the instructions on the caps and gave the older adult 5 minutes to familiarize themselves with the container and open the caps. If the older adult was unable to open the container in 5 minutes, the tester gave the older adult two “screener packages” to open. A screener package is a gasoline container with the child-resistance mechanism defeated. If the older adult was able to open both screener packages, then the test result was marked a failure, because the test showed that the child-resistance feature made the cap too difficult for the older adult to open. If the older adult could not open either screener package, then the older adult was not counted, because the older adult could not open the gas can, even with the child-resistance mechanism already defeated.

The second part of the older adult test was for older adults who opened a container in the first 5 minutes. The tester replaced the older adult's first container with an identical container. The tester then asked the older adult to open the caps according to the instructions on them. After the older

¹ The Commission voted 4–0 to approve publication of this notice as drafted.

² Staff Briefing Memorandum available at: https://www.cpsc.gov/s3fs-public/Revision-to-Childrens-Gasoline-Burn-Prevention-Act-Regulation-16-C-F-R-part-1460.pdf?VersionId=NHFcZYVIgZy5pT_SKHnGLcWfkeY8p4_O.

adult completed that step, the tester asked the older adult to close the caps on the container according to the instructions. A test where the older adult completed both tasks within 1 minute total was marked a pass, because the test showed that an older adult could open and close two child-resistant containers. Otherwise, the test was marked a failure. For the container to pass the older adult test, at least 90 percent of the older adults must have passed.

2. Requirements Introduced in ASTM F2517–15 and ASTM F2517–17

The 2015 and 2017 revisions are described in detail in the staff package. Significant elements of the 2015 revision included a new requirement that the tester tell the child to “use your teeth if you want to” during a child test. This instruction was based on testing provisions in the CPSC regulations related to the PPPA, 16 CFR 1700.20. ASTM F2517–15 also expanded the scope of the standard to include diesel and kerosene containers, as well as aftermarket components.

In 2017, to account for changes to gasoline container closures, ASTM revised the requirements to prepare containers for testing as well as the instructions given to children. ASTM F2517–17 also allowed the use of centralized testing as long as socioeconomic diversity was maintained. Testing laboratories were finding it difficult to test in daycare facilities, and centralized testing permitted increased testing options.

3. Ambiguities in Applying ASTM F2517–17

Gasoline container designs have changed considerably since 2005, primarily in response to U.S. Environmental Protection Agency (EPA) vapor emission requirements. Gasoline containers made before 2009 generally contained only one closure to refill and dispense gasoline. Typically, gasoline containers now contain two closures, one to secure the container after refilling (refilling closure) and a second within the spout to prevent vapors from escaping (dispensing closure). Gasoline containers also no longer contain a separate vent; instead, they use a venting mechanism incorporated in the dispensing closure.

When a dispensing closure on current gasoline containers is not activated, the opening automatically closes and seals in the fuel and vapors. This self-sealing closure is typically achieved using a spring-loaded mechanism. Opening the dispensing closure on EPA-compliant gasoline containers also generally

requires a more complex series of actions (e.g., insert the nozzle into receptacle, then push, then turn), compared to older gasoline containers (e.g., squeeze then turn).

The ASTM subcommittee working on the 2022 standard revision identified three ambiguities that had arisen in applying ASTM F2517–17. The first involved a failure provision relating to children “accessing liquid” in the container. This requirement was added in 2017, to account for self-sealing mechanisms on EPA-compliant gasoline containers. Laboratories, however, were uncertain whether a child passes the test who was able to open momentarily a self-sealing closure without keeping it open long enough to get liquid.

The second ambiguity involved screener packages used to determine if an older adult was an acceptable participant for testing. Prior to EPA emission limits, the screener package was typically made by replacing the child-resistant screw cap with a non-child-resistant screw cap (e.g., a screw cap with the ratchet removed) on the only closure. EPA-compliant gasoline containers, however, now also have a second closure with integrated child-resistance features, so a new approach was needed to screen older adult participants. ASTM F2517–17 did not clearly indicate a solution.

The final ambiguity involved the resealing portion of the older adult test. Older adults were given 1 minute to open and then reseal the container. EPA-compliant gasoline containers, however, now include separate dispensing closures and filling closures, and the standard did not indicate whether the dispensing closure, filling closure, or both closures, should be tested.

4. Substantive Changes to ASTM F2517

a. Accessing Liquid Failure Criteria in Child Testing

To address the ambiguity of the term “accessing liquid,” the revised standard changed the test to evaluate whether children are able to “dispense liquid” from a self-sealing closure. This new requirement maintains the understanding that a child should not gain access to the liquid, but does not necessarily fail a container with a spring-loaded closure simply because a child pressed the trigger momentarily but could not keep it open long enough to dispense liquid from the container. This revision represents an improvement over ASTM F2517–05 because it enables self-sealing solutions such as spring-loaded closures, and the momentary exposure of children to

gasoline fumes and vapors from a self-sealing closure exposes children to less fumes and vapors than a gasoline container from prior to 2009, which, by design, allowed gasoline fumes and vapors to escape.

b. Instructions to Children To Use Their Teeth

Testing laboratories indicated during the development process of ASTM F2517–22e1 that they seldom witnessed children trying to use their teeth when testing gasoline containers. Furthermore, because gasoline container closures are larger and shaped more irregularly than products like medicine bottle caps, and they rely on a sequence of actions rather than just exceeding a certain torque threshold, children are unlikely to gain a meaningful advantage by using their teeth when attempting to open a gasoline container closure. Additionally, stakeholders raised concerns that children using their teeth could sustain injuries to their mouth or swallow pieces of plastic.

Therefore, ASTM F2517–22e1 removes the instruction to encourage children to use their teeth. The standard does not prohibit children from using their teeth, so that children can interact with the closures as they choose to, including using their teeth. However, the risk of harming the children during the test is reduced, without adversely affecting the ability to ascertain the child-resistance of the container. Removing this instruction aligns with international standards.³

c. New Adult Test Replacing Previous Older Adult Test

The revised standard includes a new adult test. Adults are still given 5 minutes to read the instruction, familiarize themselves with the container, and demonstrate that it can be opened and resealed. Then the adults are given two, 1-minute periods to open and reseal each closure. However, the demographics, mixture of genders of adults, and suitability of participants have been changed to reflect more accurately those who actually use gasoline containers.

Many of the ASTM F2517–17 older adult test requirements were based on requirements for products subject to 16 CFR 1700.15(b)(2)(i) and the PPPA. However, the usage and demographics of users of gasoline containers differ from those for products subject to the PPPA, such as medicine bottles. Gasoline containers are generally used to fuel products for yard work (e.g.,

³ CSA Z76.1, ISO 8317–15, ISO 14375:2018, EN 862:2006–02.

lawn mowers, leaf blowers), and other activities (e.g., ATVs); so gasoline container users are expected to have a baseline physical ability that allows them to complete these tasks. In addition, gasoline containers are designed to be used repeatedly, so gasoline container users are expected to have some experience in their operation.

- The new adult test requirements broaden the age range of adults, rather than all participants being between 50 and 70, as in the previous older adult test. Adults between the ages of 50 and 70 are still included; the new age distribution is:

- 22%–28% are 18 to 29 years of age;
- 45%–55% are 30 to 49 years of age;

and

- 22%–28% are 50 to 70 years of age.

- The new adult test includes more men, but it still requires at least 30 percent women, rather than 70 percent women, as in the previous older adult test.

The adult test also replaces the screener package with a self-certifying question, asking adult participants if they have used a gasoline container in the last 2 years. Adults who report unfamiliarity with gasoline containers are not used for the test.

Additionally, the revised standard permits adult test participants to view videos and other informative materials that might be found on the internet to reflect better the modern methods that manufacturers use to provide information to consumers, if those test subjects attempt to find the videos. Adult participants who try to access additional information that a manufacturer has on the internet during the familiarization period of the test would be given that information by the tester. Finally, the adult test sequence specifically instructs the adult to open and reseal both the refilling and dispensing closures within 1 minute for each closure.

d. Approving a Family of Containers

In addition to addressing implementation issues that had arisen with ASTM F2517–17, ASTM F2517–22e1 allows a “family” of gasoline containers to be acceptable if the smallest container (which is very likely the easiest for children to manipulate) is tested by children and the largest container (which is very likely the hardest for children to manipulate) is tested by adults. A “family” of gasoline containers consists of containers that share the same design features, including the same child-resistance features, but in varying sizes and colors. The child-resistance features still need

to be tested, but the same features do not need to be tested repeatedly when shown to be acceptable on other containers. This revision maintains child-resistance because the child-resistance features are the same within the “family” of containers. Accordingly, if children cannot access the smallest container in the family, then it is likely they will not be able to access the larger containers in the same family.

5. Non-Substantive Revisions in ASTM F2517

In addition to clarifying ambiguities in the prior standard, as discussed above, the ASTM subcommittee made several non-substantive changes to the standard that are relevant to CPSC’s implementation of the Act. First, ASTM F2517–22e1 newly includes the terms “dispensing system,” “closure,” “filling opening,” and “portable fuel container” in the terminology section. ASTM F2517–22e1 also includes a new “requirements” section, Section 4. Requirements that are applicable to both child and adult testing were moved into this section.

Two unnecessary requirements were removed from ASTM F2517. The ASTM subcommittee removed repetitive testing steps for containers where dispensing systems may be stowed in the container. Some modern gasoline containers include a dispensing system that is stowed for sale, but is not intended or practical for the consumer to re-stow in regular use. Un-stowing a dispensing system was an unnecessary component to testing. Additionally, a requirement to seal containers 72 hours before testing was removed because statistical data indicated that the torque required to open the container did not change over time.

The readability of ASTM F2517–22e1 was improved. The protocol steps are now written in the imperative. For instance, the language stating that “the testing shall take place in a well-lit location that is or becomes familiar to the children and is isolated from all distractions” was revised to state in the imperative “conduct the testing in a test area that is well-lit and where the children are isolated from all distractions.” The test protocols also were reorganized into a consistent structure of “Test Parameters,” “Test Environment,” and “Test Panel.”

These non-substantive changes do not impact the purposes of the Act regarding the child resistance requirements, because the technical requirements that affect the determination of child resistance were not changed.

6. Change to Statutory Definition of “Portable Gasoline Container”

When Congress enacted the CGBPA in 2008, section 2(c) of the Act defined “portable gasoline container” as “any portable gasoline container intended for use by consumers.” In 2020, Congress amended the definition of “portable gasoline container,” by inserting after “for use by consumers” the following: “and any receptacle for gasoline, kerosene, or diesel fuel, including any spout, cap, and other closure mechanism and component of such receptacle or any retrofit or aftermarket spout or component intended or reasonably anticipated to be for use with such receptacle, produced or distributed for sale to or use by consumers for transport of, or refueling of internal combustion engines with, gasoline, kerosene, or diesel fuel.”⁴ The current mandatory standard incorporated the previous statutory definition at 16 CFR 1460.2. This definition is being updated to reflect the revised statutory definition. Therefore, in addition to updating the incorporation by reference to ASTM F2517–22e1, the draft final rule also updates the definition of “portable gasoline container” stated in 16 CFR 1460.2 to reflect the current statutory definition.

C. Direct Final Rule Process

The Commission is issuing this rule as a direct final rule. Although the Administrative Procedure Act (APA; 5 U.S.C. 551–559) generally requires agencies to provide notice of a rule and an opportunity for interested parties to comment on it, section 553 of the APA provides an exception when the agency “for good cause finds” that notice and comment are “impracticable, unnecessary, or contrary to the public interest.” *Id.* 553(b)(B). The Commission concludes that when it updates a reference to ASTM F2517 that is incorporated by reference under section 2(d) of the CGBPA, notice and comment are not necessary.

Specifically, under section 2(d) of the CGBPA, when ASTM revises ASTM F2517, that revision will become the new CPSC standard, unless the Commission determines that ASTM’s revision does not carry out the purposes of section 2(b) of the Act. Thus, unless the Commission makes such a determination, the ASTM revision becomes CPSC’s mandatory standard by

⁴ The amendment to this definition was contained in the Portable Fuel Container Safety Act of 2020, codified at 15 U.S.C. § 2056d, as stated Public Law 116–260, div. FF, title IX, § 901(c), available at: <https://www.govinfo.gov/content/pkg/PLAW-116/publ260/pdf/PLAW-116publ260.pdf>.

operation of law. The Commission is allowing ASTM F2517–22e1 to become CPSC’s new standard. The purpose of this direct final rule is to update the Code of Federal Regulations (CFR) so that it reflects the version of the standard that takes effect by statute. This rule updates the reference in the CFR, but under the terms of the CGBPA, ASTM F2517–22e1 takes effect as the new CPSC mandatory standard for portable fuel containers, even if the Commission does not issue this rule. Additionally, the revision of the definition of portable gasoline container in the regulation is merely to ensure the definition comports with the revised statutory definition. Thus, public comments would not alter substantive changes to the standard or the effect of the revised standard as a consumer product safety standard under section 2(b) of the CGBPA. Under these circumstances, notice and comment are unnecessary.

In Recommendation 95–4, the Administrative Conference of the United States (ACUS) endorses direct final rulemaking as an appropriate procedure to expedite rules that are noncontroversial and not expected to generate significant adverse comments. See 60 FR 43108 (Aug. 18, 1995). ACUS recommends that agencies use the direct final rule process when they act under the “unnecessary” prong of the good cause exemption in 5 U.S.C. 553(b)(B). Consistent with the ACUS recommendation, the Commission is publishing this rule as a direct final rule, because CPSC does not expect any significant adverse comments.

Unless CPSC receives a significant adverse comment by December 7, 2022, the rule will become effective on December 22, 2022. In accordance with ACUS’s recommendation, the Commission considers a significant adverse comment to be “one where the commenter explains why the rule would be inappropriate,” including an assertion challenging “the rule’s underlying premise or approach,” or a claim that the rule “would be ineffective or unacceptable without a change.” 60 FR 43108, 43111 (Aug. 18, 1995). As noted, this rule merely updates a reference in the CFR to reflect a change that occurs by statute and a change to the statutory definition of “portable fuel container,” and public comments should address these specific actions.

If the Commission receives a significant adverse comment, the Commission will withdraw this direct final rule. Depending on the comment and other circumstances, the Commission may then incorporate the adverse comment into a subsequent

direct final rule or publish a notice of proposed rulemaking, providing an opportunity for public comment.

D. Incorporation by Reference

Section 1460.3 of the direct final rule incorporates by reference ASTM F2517–22e1. The Office of the Federal Register (OFR) has regulations regarding incorporation by reference. 1 CFR part 51. Under these regulations, agencies must discuss, in the preamble to a final rule, ways in which the material the agency incorporates by reference is reasonably available to interested parties, and how interested parties can obtain the material. In addition, the preamble to the final rule must summarize the material. 1 CFR 51.5(b).

In accordance with the OFR regulations, section B. Description of the Rule of this preamble summarizes the major provisions of ASTM F2517–22e1 that the Commission incorporates by reference into 16 CFR part 1460. The standard is reasonably available to interested parties. Until the direct final rule takes effect, a read-only copy of ASTM F2517–22e1 is available for viewing, at no cost, on ASTM’s website at: www.astm.org/CPSC.htm. Once the rule takes effect, a read-only copy of the standard will be available for viewing, at no cost, on the ASTM website at: www.astm.org/READINGLIBRARY/. Interested parties can also schedule an appointment to inspect a copy of the standard at CPSC’s Office of the Secretary, U.S. Consumer Product Safety Commission, Room 820, 4330 East West Highway, Bethesda, MD 20814, telephone: (301) 504–7479; email: cpsc-os@cpsc.gov. Interested parties can purchase a copy of ASTM F2517–22e1 from ASTM International, 100 Barr Harbor Drive, P.O. Box C700, West Conshohocken, PA 19428–2959 USA; telephone: (610) 832–9585; www.astm.org.

E. Effective Date

The CGBPA provides that “the proposed revision shall be incorporated in the consumer product safety rule . . . unless, within 60 days of such notice, the Commission notifies ASTM International that the Commission has determined that such revision does not carry out the purposes” of section 2(b) of the Act. Unless the Commission receives a significant adverse comment by December 7, 2022, the rule will become effective on December 22, 2022. Portable gasoline containers manufactured or imported on or after the effective date must comply with the child-resistance requirements for closures on portable gasoline containers in ASTM F2517–22e1.

F. Certification

Section 14(a) of the CPSA requires that products subject to a consumer product safety rule under the CPSA, or to a similar rule, ban, standard, or regulation under any other act enforced by the Commission, be certified as complying with all applicable CPSC requirements. 15 U.S.C. 2063(a). Such certification must be based on a test of each product, or on a reasonable testing program. Because ASTM F2517–22e1 is considered a consumer product safety rule under the CPSA, portable gasoline containers manufactured or imported on or after December 22, 2022, are subject to the testing and certification requirements of section 14 of the CPSA with respect to ASTM F2517–22e1.

G. Regulatory Flexibility Act

The Regulatory Flexibility Act (RFA; 5 U.S.C. 601–612) generally requires agencies to review proposed and final rules for their potential economic impact on small entities, including small businesses, and prepare regulatory flexibility analyses. 5 U.S.C. 603, 604. The RFA applies to any rule that is subject to notice and comment procedures under section 553 of the APA. *Id.* As discussed in section C. Direct Final Rule Process of this preamble, the Commission has determined that notice and the opportunity to comment are unnecessary for this rule. Therefore, the RFA does not apply. CPSC also notes the limited nature of this document, which merely updates the incorporation by reference to reflect the standard that becomes mandatory under the CGBPA and to conform the definition of “portable gasoline containers” in the regulation with the revised statutory definition.

H. Environmental Considerations

The Commission’s regulations provide a categorical exclusion for the Commission’s rules from any requirement to prepare an environmental assessment or an environmental impact statement where they “have little or no potential for affecting the human environment.” 16 CFR 1021.5(c)(2). This rule falls within the categorical exclusion, so no environmental assessment or environmental impact statement is required.

I. Preemption

Section 26(a) of the CPSA provides that where a consumer product safety standard is in effect and applies to a product, no state or political subdivision of a state may either establish or continue in effect a

requirement dealing with the same risk of injury unless the state requirement is identical to the federal standard. 15 U.S.C. 2075(a). Section 26(c) of the CPSA also provides that states or political subdivisions of states may apply to CPSC for an exemption from this preemption under certain circumstances. The CGBPA deems rules issued under that statute a “consumer product safety rule.” Therefore, once a rule issued under the CGBPA takes effect, it will preempt in accordance with section 26(a) of the CPSA.

J. Congressional Review Act

The Congressional Review Act (CRA; 5 U.S.C. 801–808) states that before a rule can take effect, the agency issuing the rule must submit the rule, and certain related information, to each House of Congress and the Comptroller General. 5 U.S.C. 801(a)(1). The CRA submission must indicate whether the rule is a “major rule.” The CRA states that the Office of Information and Regulatory Affairs determines whether a rule qualifies as a “major rule.”

Pursuant to the CRA, this rule does not qualify as a “major rule,” as defined in 5 U.S.C. 804(2). To comply with the CRA, CPSC will submit the required information to each House of Congress and the Comptroller General.

List of Subjects in 16 CFR Part 1460

Consumer protection, Gasoline, Incorporation by reference, Safety.

For the reasons stated above, the Commission amends 16 CFR part 1460 as follows:

PART 1460—CHILDREN’S GASOLINE BURN PREVENTION ACT REGULATION

- 1. Revise the authority citation for part 1460 to read as follows:

Authority: Sec. 2, Pub. L. 110–278, 122 Stat. 2602; and Pub. L. 116–260, div. FF, title IX, § 901(c).

- 2. Revise § 1460.2 to read as follows:

§ 1460.2 Definition.

Portable fuel container means any portable gasoline container intended for use by consumers and any receptacle for gasoline, kerosene, or diesel fuel, including any spout, cap, and other closure mechanism and component of such receptacle or any retrofit or aftermarket spout or component intended or reasonably anticipated to be for use with such receptacle, produced or distributed for sale to or use by consumers for transport of, or refueling of internal combustion engines with, gasoline, kerosene, or diesel fuel.

- 3. Revise § 1460.3 to read as follows:

§ 1460.3 Requirements for child-resistance for closures on portable gasoline containers.

Each portable gasoline container manufactured on or after December 22, 2022 for sale in the United States shall conform to the child-resistance requirements for closures on portable gasoline containers specified in sections 2 through 7 of ASTM F2517–22e1. ASTM F2517–22e1, *Standard Specification for Determination of Child Resistance of Portable Fuel Containers for Consumer Use*, approved June 1, 2022 is incorporated by reference into this section with the approval of the Director of the Federal Register under 5 U.S.C. 552(a) and 1 CFR part 51. This material is available for inspection at the Office of the Secretary, U.S. Consumer Product Safety Commission at: Room 820, 4330 East West Highway, Bethesda, MD 20814, telephone (301) 504–7479, email cpsc-os@cpsc.gov, or at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, email fr.inspection@nara.gov, or go to: www.archives.gov/federal-register/cfr/ibr-locations.html. A read-only copy of the standard is available for viewing on the ASTM website at www.astm.org/READINGLIBRARY/. This material may be obtained from ASTM International, 100 Barr Harbor Drive, PO Box C700, West Conshohocken, PA 19428–2959; telephone (610) 832–9585; www.astm.org.

Alberta E. Mills,

Secretary, Consumer Product Safety Commission.

[FR Doc. 2022–25308 Filed 11–21–22; 8:45 am]

BILLING CODE 6355–01–P

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

21 CFR Part 1308

[Docket No. DEA–397]

Schedules of Controlled Substances: Placement of Mesocarb in Schedule I

AGENCY: Drug Enforcement Administration, Department of Justice.
ACTION: Final rule.

SUMMARY: With the issuance of this final rule, the Drug Enforcement Administration places mesocarb (chemical name: *N*-phenyl-*N'*-(3-(1-phenylpropan-2-yl)-1,2,3-oxadiazol-3-ium-5-yl)carbamimidate), including its salts, isomers, and salts of isomers, in schedule I of the Controlled Substances

Act. This action is being taken to enable the United States to meet its obligations under the 1971 Convention on Psychotropic Substances. This action imposes the regulatory controls and administrative, civil, and criminal sanctions applicable to schedule I controlled substances on persons who handle (manufacture, distribute, import, export, engage in research, conduct instructional activities or chemical analysis with, or possess), or propose to handle mesocarb.

DATES: Effective date: December 22, 2022.

FOR FURTHER INFORMATION CONTACT: Dr. Terrence L. Boos, Drug and Chemical Evaluation Section, Diversion Control Division, Drug Enforcement Administration; Telephone: (571) 362–3249.

SUPPLEMENTARY INFORMATION:

Legal Authority

The United States is a party to the 1971 United Nations Convention on Psychotropic Substances (1971 Convention), February 21, 1971, 32 U.S.T. 543, 1019 U.N.T.S. 175, as amended. Procedures respecting changes in drug schedules under the 1971 Convention are governed domestically by 21 U.S.C. 811(d)(2)–(4). When the United States receives notification of a scheduling decision pursuant to Article 2 of the 1971 Convention adding a drug or other substance to a specific schedule, the Secretary of the Department of Health and Human Services (HHS),¹ after consultation with the Attorney General, shall first determine whether existing legal controls under subchapter I of the Controlled Substances Act (CSA) and the Federal Food, Drug, and Cosmetic Act meet the requirements of the schedule specified in the notification with respect to the specific drug or substance.² Based on those determinations, as appropriate, the Secretary of HHS (Secretary) shall recommend to the Attorney General that he initiate proceedings for scheduling the drug or substance pursuant to 21 U.S.C. 811(a) and (b).³ The CSA also

¹ As discussed in a memorandum of understanding entered into by the Food and Drug Administration (FDA) and the National Institute on Drug Abuse (NIDA), FDA acts as the lead agency within HHS in carrying out the Secretary’s scheduling responsibilities under the CSA, with the concurrence of NIDA. 50 FR 9518 (March 8, 1985). The Secretary of HHS has delegated to the Assistant Secretary for Health of HHS the authority to make domestic drug scheduling recommendations. 58 FR 35460 (July 1, 1993).

² 21 U.S.C. 811(d)(3).

³ Id.

stipulates that in certain circumstances where the permanent section 811(a) scheduling will not be completed in time as required by the 1971 Convention, the Attorney General shall, after satisfying other specified conditions, issue a temporary order controlling the drug or substance under schedule IV or V, whichever is most appropriate to carry out the minimum United States obligations under the 1971 Convention.⁴

In the event that the Secretary did not so consult with the Attorney General to make a determination about the existing legal controls, and the Attorney General did not issue a temporary order, the procedures for permanent scheduling are set forth in 21 U.S.C. 811(a) and (b). Pursuant to 21 U.S.C. 811(a)(1), the Attorney General may, by rule, add to such a schedule or transfer between such schedules any drug or other substance, if he finds that such drug or other substance has a potential for abuse, and makes with respect to such drug or other substance the findings prescribed by 21 U.S.C. 812(b) for the schedule in which such drug or other substance is to be placed. The Attorney General has delegated this scheduling authority to the Administrator of the Drug Enforcement Administration (Administrator).⁵

Background

Mesocarb (chemical name: *N*-phenyl-*N'*-(3-(1-phenylpropan-2-yl)-1,2,3-oxadiazol-3-ium-5-yl)carbamimidate) is a central nervous system (CNS) stimulant.

At its 38th session (March 1995), the United Nations Commission on Narcotic Drugs added mesocarb to Schedule IV of the 1971 Convention, thus notifying all parties to the 1971 Convention.

DEA and HHS Eight Factor Analyses

On April 3, 2012, in accordance with 21 U.S.C. 811(b), and in response to the Drug Enforcement Administration's (DEA) August 12, 2008 request, HHS provided to DEA a scientific and medical evaluation and a scheduling recommendation for mesocarb. DEA subsequently reviewed HHS' evaluation and recommendation for schedule I placement and all other relevant data and conducted its own analysis under the eight factors stipulated in 21 U.S.C. 811(c). DEA found, under 21 U.S.C. 812(b)(1), that this substance warrants control in schedule I. Both DEA and HHS analyses are available in their entirety under "Supporting and Related Material" of the public docket for this

rule at <https://www.regulations.gov> under docket number DEA-397.

Notice of Proposed Rulemaking To Schedule Mesocarb

On August 11, 2021, DEA published a notice of proposed rulemaking (NPRM) entitled "Schedules of Controlled Substances: Placement of mesocarb in schedule I."⁶ The NPRM provided an opportunity for interested persons to file a request for a hearing in accordance with DEA regulations on or before September 10, 2021. No requests for such a hearing were received by DEA. The NPRM also provided an opportunity for interested persons to submit comments on the proposed rule on or before October 12, 2021.

Comments Received

DEA received two comments on the proposed rule to control mesocarb in schedule I of the CSA.

Support for rulemaking: One commenter supported the placement of mesocarb in schedule I due to the continued abuse of controlled substances.

DEA Response: DEA appreciates the comment in support of this rulemaking.

Opposition to rulemaking: One commenter opposed the placement of mesocarb in schedule I by suggesting it be placed in schedule II due to the infrequent use in the United States and its availability and use in other countries.

DEA Response: DEA does not agree. DEA is not aware of any availability or source of mesocarb in the United States, and the commenter did not provide any evidence of its use in the United States. As discussed in HHS's eight-factor analysis, mesocarb is not approved by the United States Food and Drug Administration (FDA) for use in the United States. As explained in the NPRM, the medical and scientific evaluation and scheduling recommendation issued by the Assistant Secretary for Health of HHS (Assistant Secretary) concludes that mesocarb has no currently accepted medical use in treatment in the United States and lacks accepted safety for use under medical supervision.

In addition, DEA conducted an eight-factor analysis pursuant to 21 U.S.C. 811(c), and based its scheduling determination on a comprehensive evaluation of all available data. As stated in the NPRM, after careful review of all data, DEA concurred with HHS' assessment that mesocarb has a high potential for abuse with no currently accepted medical use in treatment in the

United States and lacks accepted safety for use under medical supervision. Congress established only one schedule, schedule I, for drugs of abuse with "no currently accepted medical use in treatment in the United States" and "lack of accepted safety for use under medical supervision."⁷ The other four schedules require the drug or other substance to have a currently accepted medical use in treatment in the United States or a currently accepted medical use with severe restrictions (schedule II) or a currently accepted medical use in treatment in the United States (schedules III through V).⁸ DEA is therefore promulgating this final rule placing mesocarb in schedule I under the CSA.

Scheduling Conclusion

After consideration of the public comments, the scientific and medical evaluation and accompanying recommendation of HHS, and conducting an independent eight-factor analysis, DEA finds substantial evidence of potential for abuse of mesocarb. As such, DEA is permanently scheduling mesocarb as a controlled substance under the CSA.

Determination of Appropriate Schedule

The CSA establishes five schedules of controlled substances known as schedules I, II, III, IV, and V.⁹ The CSA also outlines the findings required to place a drug or other substance in any particular schedule.¹⁰ After consideration of the analysis and recommendation of the Assistant Secretary and review of all other available data, the Administrator, pursuant to 21 U.S.C. 811(a) and 812(b)(1), finds that:

(1) Mesocarb has a high potential for abuse. This potential is comparable to certain schedule II substances (e.g., methamphetamine or amphetamine);

(2) Mesocarb has no currently accepted medical use in treatment in the United States;¹¹ and

⁷ 21 U.S.C. 812(b).

⁸ *Id.*

⁹ 21 U.S.C. 812(a).

¹⁰ 21 U.S.C. 812(b).

¹¹ Although there is no evidence suggesting that mesocarb has a currently accepted medical use in treatment in the United States, it bears noting that a drug cannot be found to have such medical use unless DEA concludes that it satisfies a five-part test. Specifically, with respect to a drug that has not been approved by FDA, to have a currently accepted medical use in treatment in the United States, all of the following must be demonstrated: i. the drug's chemistry must be known and reproducible; ii. there must be adequate safety studies; iii. there must be adequate and well-controlled studies proving efficacy; iv. the drug must be accepted by qualified experts; and v. the scientific evidence must be widely available. 57 FR

⁴ 21 U.S.C. 811(d)(4)(A).

⁵ 28 CFR 0.100.

⁶ 86 FR 43978.

(3) There is a lack of accepted safety for use of mesocarb under medical supervision.

Based on these findings, the Administrator concludes that mesocarb, including its salts, isomers, and salts of isomers, warrants control in schedule I of the CSA.¹²

Requirements for Handling Mesocarb

Effective as of December 22, 2022, mesocarb will be subject to the CSA's schedule I regulatory controls and administrative, civil, and criminal sanctions applicable to the manufacture, distribution, dispensing, importing, exporting, research, and conduct of instructional activities, including the following:

1. *Registration.* Any person who handles (manufactures, distributes, imports, exports, engages in research, or conducts instructional activities or chemical analysis with, or possesses) mesocarb, or who desires to handle mesocarb, must be registered with DEA to conduct such activities pursuant to 21 U.S.C. 822, 823, 957, and 958, and in accordance with 21 CFR parts 1301 and 1312. Any person who handles mesocarb and is not registered with DEA must submit an application for registration and may not continue to handle mesocarb after the effective date of this rule, unless DEA has approved that application, pursuant to 21 U.S.C. 822, 823, 957, and 958 and in accordance with 21 CFR parts 1301 and 1312.

2. *Disposal of stocks.* Any person unwilling or unable to obtain a schedule I registration must surrender all quantities of mesocarb as of the effective date of this rule, or may transfer all such quantities of mesocarb to a person registered with DEA. Mesocarb is required to be disposed of in accordance with 21 CFR part 1317, in addition to all other applicable Federal, State, local, and tribal laws.

3. *Security.* Mesocarb is subject to schedule I security requirements and must be handled and stored pursuant to 21 U.S.C. 821 and 823 and in accordance with 21 CFR parts 1301.71–1301.76. Non-practitioners handling mesocarb must also comply with the employee screening requirements of 21 CFR parts 1301.90–1301.93.

4. *Labeling and Packaging.* All labels, labeling, and packaging for commercial containers of mesocarb must comply with 21 U.S.C. 825 and be in accordance with 21 CFR part 1302.

5. *Quota.* Only registered manufacturers are permitted to manufacture mesocarb in accordance with a quota assigned pursuant to 21 U.S.C. 826 and in accordance with 21 CFR part 1303.

6. *Inventory.* Every DEA registrant who possesses any quantity of mesocarb must take an inventory of mesocarb on hand pursuant to 21 U.S.C. 827, and in accordance with 21 CFR parts 1304.03, 1304.04, and 1304.11(a) and (d).

Any person who registers with DEA must take an initial inventory of all stocks of controlled substances (including mesocarb) on hand on the date the registrant first engages in the handling of controlled substances, pursuant to 21 U.S.C. 827, 958, and in accordance with 21 CFR parts 1304.03, 1304.04, and 1304.11(a) and (b).

After the initial inventory, every DEA registrant must take an inventory of all controlled substances (including mesocarb) on hand every two years, pursuant to 21 U.S.C. 827, and in accordance with 21 CFR parts 1304.03, 1304.04, and 1304.11.

7. *Records and Reports.* Every DEA registrant must maintain records and submit reports with respect to mesocarb, pursuant to 21 U.S.C. 827, and in accordance with 21 CFR 1301.74(b) and (c) and 1301.76(b), and parts 1304, 1312, and 1317. Manufacturers and distributors must submit reports regarding mesocarb to the Automation of Reports and Consolidated Order System pursuant to 21 U.S.C. 827 and in accordance with 21 CFR parts 1304 and 1312.

8. *Order Forms.* Every DEA registrant who distributes or orders mesocarb must comply with the order form requirements, pursuant to 21 U.S.C. 828 and in accordance with 21 CFR part 1305.

9. *Importation and Exportation.* All importation and exportation of mesocarb must comply with 21 U.S.C. 952, 953, 957, and 958, and in accordance with 21 CFR part 1312.

10. *Liability.* Any activity involving mesocarb not authorized by, or in violation of, the CSA or its implementing regulations, is unlawful, and may subject the person to administrative, civil, and/or criminal sanctions.

Regulatory Analyses

Executive Orders 12866 (Regulatory Planning and Review) and 13563 (Improving Regulation and Regulatory Review)

In accordance with 21 U.S.C. 811(a), this final scheduling action is subject to formal rulemaking procedures

performed “on the record after opportunity for a hearing,” which are conducted pursuant to the provisions of 5 U.S.C. 556 and 557. The CSA sets forth the criteria for scheduling a drug or other substance. Such actions are exempt from review by the Office of Management and Budget (OMB) pursuant to section 3(d)(1) of Executive Order (E.O.) 12866 and the principles reaffirmed in E.O. 13563.

Executive Order 12988, Civil Justice Reform

This regulation meets the applicable standards set forth in sections 3(a) and 3(b)(2) of E.O. 12988 to eliminate drafting errors and ambiguity, minimize litigation, provide a clear legal standard for affected conduct, and promote simplification and burden reduction.

Executive Order 13132, Federalism

This rulemaking does not have federalism implications warranting the application of E.O. 13132. The rule does not have substantial direct effects on the States, on the relationship between the National Government and the States, or the distribution of power and responsibilities among the various levels of government.

Executive Order 13175, Consultation and Coordination With Indian Tribal Governments

This rule does not have tribal implications warranting the application of E.O. 13175. It does not have substantial direct effects on one or more Indian tribes, on the relationship between the Federal Government and Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes.

Regulatory Flexibility Act

The Administrator, in accordance with the Regulatory Flexibility Act, 5 U.S.C. 601–612, has reviewed this final rule and by approving it certifies that it will not have a significant economic impact on a substantial number of small entities.

DEA is placing the substance mesocarb, including its salts, isomers, and salts of isomers, in schedule I of the CSA. This action is being taken to enable the United States to meet its obligations under the 1971 Convention. This action imposes the regulatory controls and administrative, civil, and criminal sanctions applicable to schedule I controlled substances on persons who handle (manufacture, distribute, reverse distribute, import, export, engage in research, conduct instructional activities or chemical

10499 (1992), *pet. for rev. denied*, *Alliance for Cannabis Therapeutics v. DEA*, 15 F.3d 1131, 1135 (D.C. Cir. 1994).

¹² 21 U.S.C. 812(b)(1).

analysis with, or possess) mesocarb, or propose to handle mesocarb.

Based on the review of HHS' scientific and medical evaluation and all other relevant data, DEA determined that mesocarb has a high potential for abuse, has no currently accepted medical use in treatment in the United States, and lacks accepted safety for use under medical supervision. DEA's research confirms that there is no legitimate commercial market for mesocarb in the United States. Therefore, DEA estimates that no United States entity currently handles mesocarb and does not expect any United States entity to handle mesocarb in the foreseeable future. DEA concludes that no legitimate United States entity would be affected by this rule. As such, this rule will not have a significant effect on a substantial number of small entities.

Unfunded Mandates Reform Act of 1995

In accordance with the Unfunded Mandates Reform Act (UMRA) of 1995, 2 U.S.C. 1501 *et seq.*, DEA has determined and certifies that this action would not result in any Federal mandate that may result "in the

expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of \$100,000,000 or more (adjusted annually for inflation) in any 1 year * * *." Therefore, neither a Small Government Agency Plan nor any other action is required under UMRA of 1995.

Congressional Review Act

This rule is not a major rule as defined by the Congressional Review Act (CRA), 5 U.S.C. 804. However, pursuant to the CRA, DEA is submitting a copy of this final rule to both Houses of Congress and to the Comptroller General.

Signing Authority

This document of the Drug Enforcement Administration was signed on November 14, 2022, by Administrator Anne Milgram. That document with the original signature and date is maintained by DEA. For administrative purposes only, and in compliance with requirements of the Office of the Federal Register, the undersigned DEA Federal Register Liaison Officer has been authorized to sign and submit the document in

electronic format for publication, as an official document of DEA. This administrative process in no way alters the legal effect of this document upon publication in the **Federal Register**.

List of Subjects in 21 CFR Part 1308

Administrative practice and procedure, Drug traffic control, Reporting and recordkeeping requirements.

For the reasons set out above, 21 CFR part 1308 is amended as follows:

PART 1308—SCHEDULES OF CONTROLLED SUBSTANCES

- 1. The authority citation for 21 CFR part 1308 continues to read as follows:
Authority: 21 U.S.C. 811, 812, 871(b), 956(b), unless otherwise noted.
- 2. Amend § 1308.11 by redesignating paragraphs (f)(7) through (10) as paragraphs (f)(8) through (11) and adding a new paragraph (f)(7) to read as follows:

§ 1308.11 Schedule I.
* * * * *
(f) * * *

(7) Mesocarb (N-phenyl-N'-(3-(1-phenylpropan-2-yl)-1,2,3-oxadiazol-3-ium-5-yl)carbamimidate) 1227

* * * * *

Scott Brinks,
Federal Register Liaison Officer, Drug
Enforcement Administration.
[FR Doc. 2022–25219 Filed 11–21–22; 8:45 am]
BILLING CODE 4410–09–P

DEPARTMENT OF STATE

22 CFR Part 126

[Public Notice: 11858]

RIN 1400–AF58

International Traffic in Arms
Regulations: Prohibited Exports,
Imports, and Sales to or From Certain
Countries—Cyprus

AGENCY: Department of State.

ACTION: Final rule.

SUMMARY: The Department of State is amending the International Traffic in Arms Regulations (ITAR) to reflect current defense trade policy towards Cyprus.

DATES: This rule is effective November 22, 2022.

FOR FURTHER INFORMATION CONTACT:
Sarah Heidema, Office of Defense Trade
Controls Policy, Department of State,
telephone (202) 663–1282, or email

DDTCCustomerService@state.gov.
ATTN: Regulatory Change, ITAR
Section 126.1 Cyprus Country Policy
Update.

SUPPLEMENTARY INFORMATION: Section 1250A(d) of the National Defense Authorization Act for Fiscal Year 2020 (Pub. L. 116–92) and section 205(d) of the Eastern Mediterranean Security and Energy Partnership Act of 2019 (Pub. L. 116–94, Div. J.) provide that the policy of denial for exports, re-exports, and transfers of defense articles on the United States Munitions List to the Republic of Cyprus shall remain in place unless the President determines and certifies to the appropriate congressional committees not less than annually that: (A) the Government of the Republic of Cyprus is continuing to cooperate with the United States Government in efforts to implement reforms on anti-money laundering regulations and financial regulatory oversight; and (B) the Government of the Republic of Cyprus has made and is continuing to take the steps necessary to deny Russian military vessels access to ports for refueling and servicing.

On April 14, 2020, the President delegated to the Secretary of State the functions and authorities vested by section 1250A(d) of the National Defense Authorization Act for Fiscal

Year 2020 (Pub. L. 116–92) and section 205(d) of the Eastern Mediterranean Security and Energy Partnership Act of 2019 (Pub. L. 116–94, Div. J.) (85 FR 35797, June 12, 2020). On September 12, 2022, utilizing these authorities, the Secretary of State certified to the appropriate congressional committees that the Republic of Cyprus meets the statutory requirements to remove the policy of denial for exports, re-exports, and transfers of defense articles to the Republic of Cyprus for fiscal year 2023. The Secretary of State further approved the suspension of the policy of denial for exports, reexports, and transfers of defense articles and defense services to the Republic of Cyprus for fiscal year 2023. In conjunction with the Secretary of State's decision, the Under Secretary for Arms Control and International Security used the Department's delegated authority (Executive Order 13637) under the Arms Export Control Act (22 U.S.C. 2751 *et seq.*) to suspend the policy of denial for retransfers and temporary imports destined for or originating in the Republic of Cyprus and brokering activities involving the Republic of Cyprus for fiscal year 2023. Accordingly, the Department now amends section 126.1 of the International Traffic in Arms Regulations (22 CFR parts 120 through

130) to specify that the Republic of Cyprus' status as a proscribed destination is suspended from October 1, 2022, through September 30, 2023. As a result of this change, certain exemptions to licensing requirements are now available for exports, re-exports, retransfers, and temporary imports destined for or originating in the Republic of Cyprus and brokering activities involving the Republic of Cyprus, provided the conditions for use of those exemptions are met. Applications for licenses and other authorizations submitted to the Directorate of Defense Trade Controls involving the Republic of Cyprus and nationals of the Republic of Cyprus are subject to case-by-case review.

Regulatory Analysis and Notices

Administrative Procedure Act

The Department of State (the Department) is of the opinion that controlling the import and export of defense articles and services is a military or foreign affairs function of the United States Government and that rules implementing this function are exempt from sections 553 (rulemaking) and 554 (adjudications) of the Administrative Procedure Act (APA), pursuant to 5 U.S.C. 553(a)(1). Since the Department is of the opinion that this rule is exempt from 5 U.S.C. 553, it is the view of the Department that the provisions of section 553 do not apply to this rulemaking.

Regulatory Flexibility Act

Since this rule is exempt from the notice-and-comment provisions of 5 U.S.C. 553(b), it does not require analysis under the Regulatory Flexibility Act.

Unfunded Mandates Reform Act of 1995

This rulemaking does not involve a mandate that will result in the expenditure by state, local, and tribal governments, in the aggregate, or by the private sector, of \$100 million or more in any year and it will not significantly or uniquely affect small governments. Therefore, no actions are deemed necessary under the provisions of the Unfunded Mandates Reform Act of 1995.

Congressional Review Act

The Department does not believe this rulemaking is a major rule within the definition of 5 U.S.C. 804.

Executive Orders 12372 and 13132

This rulemaking will not have substantial direct effects on the States, on the relationship between the national government and the States, or on the

distribution of power and responsibilities among the various levels of government. Therefore, in accordance with Executive Order 13132, it is determined that this amendment does not have sufficient federalism implications to require consultations or warrant the preparation of a federalism summary impact statement. The regulations implementing Executive Order 12372 regarding intergovernmental consultation on Federal programs and activities do not apply to this rulemaking.

Executive Orders 12866 and 13563

Executive Orders 12866 and 13563 direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributed impacts, and equity). Because the scope of this rule does not impose additional regulatory requirements or obligations, the Department believes costs associated with this rule will be minimal. This rule has been designated a "significant regulatory action" by the Office and Information and Regulatory Affairs under Executive Order 12866.

Executive Order 12988

The Department reviewed this rulemaking in light of Executive Order 12988 to eliminate ambiguity, minimize litigation, establish clear legal standards, and reduce burden.

Executive Order 13175

The Department determined that this rulemaking will not have tribal implications, will not impose substantial direct compliance costs on Indian tribal governments, and will not preempt tribal law. Accordingly, the requirements of Executive Order 13175 do not apply to this rulemaking.

Paperwork Reduction Act

This rule does not impose or revise any information collections subject to 44 U.S.C. chapter 35.

List of Subjects in 22 CFR Part 126.

Arms and munitions, exports.

Accordingly, for the reasons set forth above, Title 22, Chapter I, Subchapter M, part 126 is amended as follows:

PART 126—GENERAL POLICIES AND PROVISIONS

■ 1. The authority citation for part 126 is revised to read as follows:

Authority: 22 U.S.C. 287c, 2651a, 2752, 2753, 2776, 2778, 2779, 2779a, 2780, 2791, 2797; Sec. 1225, Pub. L. 108–375, 118 Stat. 2091; Sec. 7045, Pub. L. 112–74, 125 Stat. 1232; Sec. 1250A, Pub. L. 116–92, 133 Stat. 1665; Sec. 205, Pub. L. 116–94, 133 Stat. 3052; E.O. 13637, 78 FR 16129, 3 CFR, 2013 Comp., p. 223.

■ 2. Amend § 126.1 by adding paragraph (r) to read as follows:

§ 126.1

* * * * *

(r) *Cyprus*. It is the policy of the United States to deny licenses or other approvals for exports or imports of defense articles and defense services destined for or originating in Cyprus, except that a license or other approval may be issued, on a case-by-case basis, for the United Nations Forces in Cyprus (UNFICYP) or for civilian end-users. This policy of denial, and the status of Cyprus as a proscribed destination, is suspended from October 1, 2022, through September 30, 2023.

* * * * *

Bonnie Jenkins,

Under Secretary, Arms Control and International Security, Department of State.

[FR Doc. 2022–25541 Filed 11–21–22; 8:45 am]

BILLING CODE 4710–25–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 100

[Docket No. USCG–2022–0921]

Special Local Regulations; San Diego Parade of Lights, San Diego, CA

AGENCY: Coast Guard, DHS.

ACTION: Notification of enforcement of regulation.

SUMMARY: The Coast Guard will enforce the San Diego Parade of Lights special local regulations on the waters of San Diego Bay, California on December 11, 2022 and December 18, 2022. These special local regulations are necessary to provide for the safety of the participants, crew, spectators, sponsor vessels, and general users of the waterway. During the enforcement period, persons and vessels are prohibited from anchoring, blocking, loitering, or impeding within this regulated area unless authorized by the Captain of the Port Sector San Diego or a designated representative.

DATES: The regulations in 33 CFR 100.1101 will be enforced from 4 p.m. through 8:30 p.m. on December 11, 2022

and from 4 p.m. through 8:30 p.m. on December 18, 2022 for Item 5 in Table 1 of Section 100.1101.

FOR FURTHER INFORMATION CONTACT: If you have questions about this publication of enforcement, call or email Lieutenant Junior Grade Shera Kim, Waterways Management, U.S. Coast Guard Sector San Diego, CA; telephone (619) 278-7656, email MarineEventsSD@uscg.mil.

SUPPLEMENTARY INFORMATION:

The Coast Guard will enforce the special local regulations in 33 CFR 100.1101 for the San Diego Parade of Lights in San Diego Bay, CA in 33 CFR 100.1101, Table 1, Item 5 of that section from 4p.m. until 8:30 p.m. on December 11, 2022 and on December 18, 2022. This enforcement action is being taken to provide for the safety of life on navigable waterways during the event. The Coast Guard's regulation for recurring marine events in the San Diego Captain of the Port Zone identifies the regulated entities and area for this event. During the enforcement periods and under the provisions of 33 CFR 100.1101, persons and vessels are prohibited from anchoring, blocking, loitering, or impeding within this regulated area, unless authorized by the Captain of the Port, or his designated representative. The Coast Guard may be assisted by other Federal, State, or local law enforcement agencies in enforcing this regulation.

In addition to this document in the **Federal Register**, the Coast Guard will provide the maritime community with advance notification of this enforcement period via the Local Notice to Mariners, marine information broadcasts, and local advertising by the event sponsor.

Dated: November 16, 2022.

J.W. Spittler,

Captain, U.S. Coast Guard, Captain of the Port Sector San Diego.

[FR Doc. 2022-25427 Filed 11-21-22; 8:45 am]

BILLING CODE 9110-04-P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 165

[Docket Number USCG-2022-0857]

RIN 1625-AA00

Safety Zone; Ohio River Mile Marker 0.3-1.5, Pittsburgh, PA

AGENCY: Coast Guard, DHS.

ACTION: Temporary final rule.

SUMMARY: The Coast Guard is establishing a temporary safety zone for the Ohio River mile marker 0.3-1.5. This action is necessary to provide for the safety of life on these navigable waters during drilling operations from November 28, 2022 until December 3, 2022. This rulemaking would prohibit persons and vessels from being in the safety zone, create a slow speed/no wake zone and limit commercial traffic to one way passing unless authorized by the Captain of the Port Pittsburgh or a designated representative. The safety zone is needed to protect personnel and vessels from potential hazards created by working in the Ohio River channel.

DATES: This rule is effective from 6 a.m. November 28, 2022 through 11:59 p.m. on December 3, 2022.

ADDRESSES: To view documents mentioned in this preamble as being available in the docket, go to <https://www.regulations.gov>, type USCG-2022-0857 in the search box and click "Search." Next, in the Document Type column, select "Supporting & Related Material."

FOR FURTHER INFORMATION CONTACT: If you have questions on this rule, call or email MST1 Onnalee Blackledge, Marine Safety Unit Pittsburgh, U.S. Coast Guard, at telephone 412-221-0807 ext 222, email Onnalee.A.Blackledge@uscg.mil.

SUPPLEMENTARY INFORMATION:

I. Table of Abbreviations

CFR Code of Federal Regulations
DHS Department of Homeland Security
FR Federal Register
NPRM Notice of proposed rulemaking
§ Section
U.S.C. United States Code

II. Background Information and Regulatory History

The Coast Guard is issuing this temporary rule without prior notice and opportunity to comment pursuant to authority under section 4(a) of the Administrative Procedure Act (APA) (5 U.S.C. 553(b)). This provision authorizes an agency to issue a rule without prior notice and opportunity to comment when the agency for good cause finds that those procedures are "impracticable, unnecessary, or contrary to the public interest." Under 5 U.S.C. 553(b)(B), the Coast Guard finds that good cause exists for not publishing a notice of proposed rulemaking (NPRM) with respect to this rule because it is impracticable. The safety zone must be established by November 28, 2022 and we lack sufficient time to provide a reasonable comment period and then consider those comments before issuing

this rule. The NPRM process would delay the establishment of the safety zones until after the scheduled date for the drilling operations.

Under 5 U.S.C. 553(d)(3), the Coast Guard finds that good cause exists for making this rule effective less than 30 days after publication in the **Federal Register**. Delaying the effective date of this rule would be impracticable because this action is necessary to ensure the safety of vessels and persons during the drilling operations on November 28, 2022.

III. Legal Authority and Need for Rule

The Coast Guard is issuing this rule under authority in 46 U.S.C. 70034 (previously 33 U.S.C. 1231). The Captain of the Port Marine Safety Unit Pittsburgh (COTP) has determined that a safety zone from mile marker 0.3 to 1.5 is needed to protect personnel, vessels, and the marine environment from potential hazards created from drilling operations starting November 28, 2022 until December 3, 2022.

IV. Discussion of the Rule

This rule establishes a safety zone on from 6 a.m. on November 28, 2022 through 11:59 p.m. on December 3, 2022. The safety zone will cover all navigable waters on the Ohio River between mile marker 0.3 and 1.5, it would create a slow speed/no wake zone and limit commercial traffic to one way passing. The duration of the safety zone is intended to protect personnel, vessels, and the marine environment from potential hazards created by drilling operations.

No vessel or person is permitted to enter the safety zone without obtaining permission from the COTP or a designated representative. A designated representative is a commissioned, warrant, or petty officer of the U.S. Coast Guard (USCG) assigned to units under the operational control of the COTP. To seek permission to enter, contact the COTP or a designated representative via VHF-FM channel 16, or through Marine Safety Unit Pittsburgh at 412-221-0807. Persons and vessels permitted to enter the safety zone must comply with all lawful orders or directions issued by the COTP or designated representative. The COTP or a designated representative will inform the public of the effective period for the safety zone as well as any changes in the dates and times of enforcement through Local Notice to Mariners (LNMs), Broadcast Notices to Mariners (BNMs), and/or Marine Safety Information Bulletins (MSIBs), as appropriate.

V. Regulatory Analyses

We developed this rule after considering numerous statutes and Executive orders related to rulemaking. Below we summarize our analyses based on a number of these statutes and Executive orders, and we discuss First Amendment rights of protestors.

A. Regulatory Planning and Review

Executive Orders 12866 and 13563 direct agencies to assess the costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits. This rule has not been designated a “significant regulatory action,” under Executive Order 12866. Accordingly, this rule has not been reviewed by the Office of Management and Budget (OMB).

This regulatory action determination is based on the size, location, and duration of the temporary safety zone. This safety zone impacts only a 1.2 mile stretch of the Ohio River for 24 hours a day starting November 28, 2022 at 6 a.m. until December 3, 2022 at 11:59 p.m. Vessel traffic will be informed about the safety zone through local notices to mariners. Moreover, the Coast Guard will issue LNM, MSIB, and/or BNM via VHF-FM marine channel 16 about the zone and the rule allows vessels to seek permission from the COTP to transit the zone.

B. Impact on Small Entities

The Regulatory Flexibility Act of 1980, 5 U.S.C. 601–612, as amended, requires Federal agencies to consider the potential impact of regulations on small entities during rulemaking. The term “small entities” comprises small businesses, not-for-profit organizations that are independently owned and operated and are not dominant in their fields, and governmental jurisdictions with populations of less than 50,000. The Coast Guard certifies under 5 U.S.C. 605(b) that this rule will not have a significant economic impact on a substantial number of small entities.

While some owners or operators of vessels intending to transit the temporary safety zone may be small entities, for the reasons stated in section V.A above, this rule will not have a significant economic impact on any vessel owner or operator.

Under section 213(a) of the Small Business Regulatory Enforcement Fairness Act of 1996 (Pub. L. 104–121), we want to assist small entities in understanding this rule. If the rule would affect your small business, organization, or governmental

jurisdiction and you have questions concerning its provisions or options for compliance, please call or email the person listed in the **FOR FURTHER INFORMATION CONTACT** section.

Small businesses may send comments on the actions of Federal employees who enforce, or otherwise determine compliance with, Federal regulations to the Small Business and Agriculture Regulatory Enforcement Ombudsman and the Regional Small Business Regulatory Fairness Boards. The Ombudsman evaluates these actions annually and rates each agency’s responsiveness to small business. If you wish to comment on actions by employees of the Coast Guard, call 1–888–REG–FAIR (1–888–734–3247). The Coast Guard will not retaliate against small entities that question or complain about this rule or any policy or action of the Coast Guard.

C. Collection of Information

This rule will not call for a new collection of information under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520).

D. Federalism and Indian Tribal Governments

A rule has implications for federalism under Executive Order 13132, Federalism, if it has a substantial direct effect on the States, on the relationship between the National Government and the States, or on the distribution of power and responsibilities among the various levels of government. We have analyzed this rule under that Order and have determined that it is consistent with the fundamental federalism principles and preemption requirements described in Executive Order 13132.

Also, this rule does not have tribal implications under Executive Order 13175, Consultation and Coordination with Indian Tribal Governments, because it does not have a substantial direct effect on one or more Indian tribes, on the relationship between the Federal Government and Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes.

E. Unfunded Mandates Reform Act

The Unfunded Mandates Reform Act of 1995 (2 U.S.C. 1531–1538) requires Federal agencies to assess the effects of their discretionary regulatory actions. In particular, the Act addresses actions that may result in the expenditure by a State, local, or tribal government, in the aggregate, or by the private sector of \$100,000,000 (adjusted for inflation) or more in any one year. Though this rule will not result in such an expenditure,

we do discuss the effects of this rule elsewhere in this preamble.

F. Environment

We have analyzed this rule under Department of Homeland Security Directive 023–01, Rev. 1, associated implementing instructions, and Environmental Planning COMDTINST 5090.1 (series), which guide the Coast Guard in complying with the National Environmental Policy Act of 1969 (42 U.S.C. 4321–4370f), and have determined that this action is one of a category of actions that do not individually or cumulatively have a significant effect on the human environment. This rule involves a safety zone lasting from 6 a.m. on November 28, 2022 until 11:59 p.m. on December 3, 2022 that will prohibit entry on the Ohio River between mile marker 0.3 and 1.5, create a slow speed/no wake zone and limit commercial traffic to one way passing during drilling operations. It is categorically excluded from further review under paragraph L60(A) of Appendix A, Table 1 of DHS Instruction Manual 023–01–001–01, Rev. 1. A Record of Environmental Consideration supporting this determination is available in the docket. For instructions on locating the docket, see the **ADDRESSES** section of this preamble.

G. Protest Activities

The Coast Guard respects the First Amendment rights of protestors. Protesters are asked to call or email the person listed in the **FOR FURTHER INFORMATION CONTACT** section to coordinate protest activities so that your message can be received without jeopardizing the safety or security of people, places or vessels.

List of Subjects in 33 CFR Part 165

Harbors, Marine safety, Navigation (water), Reporting and recordkeeping requirements, Security measures, Waterways.

For the reasons discussed in the preamble, the Coast Guard amends 33 CFR part 165 as follows:

PART 165—REGULATED NAVIGATION AREAS AND LIMITED ACCESS AREAS

■ 1. The authority citation for part 165 continues to read as follows:

Authority: 46 U.S.C. 70034, 70051; 33 CFR 1.05–1, 6.04–1, 6.04–6, and 160.5; Department of Homeland Security Delegation No. 00170.1, Revision No. 01.2.

■ 2. Add § 165.T08–0857 to read as follows:

§ 165.T08–0922 Safety Zone; Ohio River, Miles 0.3–1.5, Pittsburgh, PA.

(a) *Location.* The following area is a temporary safety zone: all navigable waters of the Ohio River between Mile Marker 0.3 and Mile Marker 1.5.

(b) *Definitions.* As used in this section, *designated representative* means a Coast Guard Patrol Commander, including a Coast Guard coxswain, petty officer, or other officer operating a Coast Guard vessel and a Federal, State, and local officer designated by or assisting the Captain of the Port Pittsburgh (COTP) in the enforcement of the safety zone.

(c) *Regulations.* (1) Under the general safety zone regulations in subpart C of this part, you may not enter the safety zone described in paragraph (a) of this section unless authorized by the COTP or the COTP's designated representative.

(2) To seek permission to enter, contact the COTP or the COTP's representative by phone at 412–221–0807. Those in the safety zone must comply with all lawful orders or directions given to them by the COTP or the COTP's designated representative.

(d) *Enforcement period.* This section is effective from 6 a.m. on November 28, 2022, through 11:59 p.m. on December 3, 2022.

Dated: November 16, 2022

Justin R. Jolley,

Lieutenant Commander, U.S. Coast Guard, Acting, Captain of the Port Marine Safety Unit Pittsburgh.

[FR Doc. 2022–25416 Filed 11–21–22; 8:45 am]

BILLING CODE 9110–04–P

DEPARTMENT OF VETERANS AFFAIRS

38 CFR Part 17

RIN 2900–AR31

Readjustment Counseling Service Scholarship Program

AGENCY: Department of Veterans Affairs.

ACTION: Final rule.

SUMMARY: The Department of Veterans Affairs (VA) is adding new regulations that govern scholarship programs that will benefit certain health care professionals. This rulemaking implements the mandates of the Commander John Scott Hannon Veterans Mental Health Care Improvement Act of 2019 by establishing the Readjustment Counseling Service Scholarship Program (RCSSP). The RCSSP provides educational assistance to individuals who pursue a graduate degree in

psychology, social work, marriage and family therapy, or mental health counseling that meet the education requirements for appointment as a health care professional in one of the aforementioned fields in VA Vet Centers.

DATES: This rule is effective December 22, 2022.

FOR FURTHER INFORMATION CONTACT: Charles Flora, Social Science Specialist, Readjustment Counseling Services, 810 Vermont Ave. NW, Washington, DC 20420, (202) 461–6525. (This is not a toll-free telephone number.)

SUPPLEMENTARY INFORMATION: On November 5, 2021, VA published a proposed rule in the **Federal Register** (86 FR 81094) that would establish the Readjustment Counseling Service Scholarship Program (RCSSP) in 38 CFR 17.545 through 17.553 pursuant to section 502 of Public Law 116–171, the Commander John Scott Hannon Veterans Mental Health Care Improvement Act of 2019 (the Act), enacted on October 17, 2020. The Act established new sections 7698 through 7699B and created the RCSSP to serve as an incentive to individuals who are pursuing a graduate degree in psychology, social work, marriage and family therapy, or mental health counseling to fill existing vacancies in Vet Centers that are located in areas that are designated as medically underserved populations and in States with a per capita population of more than five percent veterans according to the National Center for Veterans Analysis and Statistics and the Bureau of the Census (42 U.S.C. 254b(b)(3)).

VA provided a 60-day comment period, which ended on January 4, 2022. VA received two comments on the proposed rule. One comment was supportive of the rule. We thank the commenter for their support and do not make any changes based on the comment.

The other comment was supportive of the rule but expressed concern about the amount of funding for psychology doctoral students and the supervision requirements in the rule. VA stated in proposed § 17.549(c) that VA would fund RCSSP for social work, marriage and family therapy, professional mental health counseling, and psychology graduate students for a maximum of two years. The commenter suggested that VA increase the RCSSP funding period for psychology students to be commensurate with their increased experience, training, and value and to account for the fact that the other occupations only require a two-year degree whereas a psychology degree is

five years, thereby leaving psychology participants with potentially significant debt compared to their counterparts in the other occupations. The commenter was concerned that psychology students could be dissuaded from participating in the RCSSP if they will still carry significant debt after graduation.

VA has considered the issues presented by the commenter, however, we reiterate from the proposed rule that the two-year limit on funding is intended to equalize the award and obligated service requirements across all four health care professions. VA believes that the two-year limit will provide full parity across the four disciplines to all scholarship awardees and provide for the equitable recruitment of individuals in the four health care professions. In this regard, the Act requires a six-year period of obligated service following the completion of the program of study. 38 U.S.C. 7699(c)(2). Therefore, VA believes it would be inequitable to fund two years for certain participants and five for others when all participants will have the same six-year period of obligated service. VA also does not believe that the two-year period for the scholarship will dissuade psychology graduates from participating in the RCSSP. We are not making any changes based on this comment.

The commenter also had concerns regarding supervision. Because VA health care professionals may be licensed in any State and not every Vet Center employs professionals from each of the professions, proposed § 17.549(b) stated that when determining which Vet Center a scholarship recipient would be placed to carry out their service obligation, VA would consider the size and professional makeup of the current Vet Center staff to ensure appropriate supervision as required by VA professional qualification standards and for State licensure. The commenter was concerned that the unintended result of the proposed rule could be that the Vet Centers with the greatest need for additional mental health professionals will be left out because of inadequate staffing levels to supervise a scholarship recipient. The commenter acknowledged that each participant requires supervision by another professional in the same discipline who is also licensed in the State they seek to gain licensure in order to obtain their license and stated that it is important that the individual requirements of each State's licensing board be considered when placing scholarship recipients. The commenter further stated that any potential solution must prioritize State licensure for the scholarship recipient

and high-quality care for veterans. The commenter encouraged VA to allow scholarship recipients to be supervised by another VA health care professional or even a community health care professional if no appropriate supervisor is available at a Vet Center. The commenter also recommended that VA split a scholarship recipient's service obligation between two sites; one site with appropriately licensed health care professionals for the scholarship recipient to gain State licensure and another in a medically underserved veteran dense community as required in § 17.549(b).

We agree with the commenter that the requirement for recipients to receive supervision from a licensed staff within their respective professions who has the necessary State license, as a condition for their own licensure, is a critical point for the consideration of the potential location of the obligated service. VA would assist the participants in making certain that they have all of the resources needed to obtain a State license. We note that proposed § 17.549(b) does not require a certain level of staffing in a Vet Center, but does require that the Vet Center have adequate staff for the purposes of supervision of participants. This requirement will ensure that all recipients can utilize their experience at the Vet Center toward obtaining their desired State license.

Regarding the commentor's recommendation that the participant be supervised by a health care professional that is not in the same health care profession as the participant, we respectfully disagree with this recommendation. It is both a VA and a requirement in some States for some of the disciplines that the health care professional be supervised by an individual within the same health care profession. Having a supervisor that is not in the same health care profession may lead to the participant not being able to obtain a State license and thus making them in violation of their agreement. VA would also not allow participants to be supervised by health care professionals in the community as these individuals are not VA employees appointed under 38 U.S.C. 7306, 7401, 7405, 7406, 7408, or title 5, U.S. Code.

We also agree with the commenter that the goal of the RCSSP is to help fill vacancies in medically underserved communities. However, we believe that splitting locations of assignment for the scholarship participant would defeat the purpose of the RCSSP, which is to provide mental health care professionals to Vet Centers that are in medically underserved areas or in States with a

per capita population of more than five percent veterans. Splitting the locations of assignment would reduce the amount of time a participant would provide vital health care services to a Vet Center location in these areas. In addition, the rapid turnover in order to accommodate two locations could negatively impact services to veterans by undermining active case coordination. We are not making any changes based on this comment.

The commenter also encouraged VA to advertise the VA Health Professional Scholarship Program (HPSP) to psychology students who are newly eligible and requested VA educate Veterans Integrated Services Network (VISN) and VA medical facility directors on the importance of offering Education Debt Reduction Program (EDRP) funds to psychologists. However, the HPSP and EDRP are beyond the scope of the proposed rule. We are not making any changes based on this comment.

VA is making a technical correction to § 17.549(b) for clarity. Proposed paragraph (b) stated when determining which Vet Center a scholarship recipient will be placed to carry out their service obligation, VA will consider the priority criteria in paragraph (a) of this section and the size and professional makeup of the current Vet Center staff to ensure that the Vet Center staff has health care professionals that are licensed to supervise participants of the RCSSP from the same health care profession as required by VA professional qualification standards for licensure for each of the four professions. We note that the text as proposed may be confusing as to whether the supervision of a health care professional from the same health care profession is a VA or State requirement. To clearly provide that the supervision is both a VA and a requirement of some States for some disciplines, we are now stating that the supervision requirements are required by VA professional qualification standards and a requirement of some State licensure boards for some disciplines for each of the four professions. No other changes to the meaning of this paragraph are intended by this change.

VA is making a technical correction to § 17.549(c)(2) for clarity. Proposed paragraph (c)(2) stated in part that psychology graduates are required to undergo a one-year residency at either an American Psychology Association (APA) or Canadian Psychological Association (CPA) accredited internship program prior to qualifying for full time VA employment. We are clarifying that the one-year residency at either an APA

or CPA should have instead stated a one-year internship. This technical correction will change the term residency to internship to make the term consistent throughout paragraph (c)(2). No other changes to the meaning of this paragraph are intended by this change.

VA is also making technical edits to § 17.553(b) for clarity. Proposed paragraph (b) stated that "except as provided in paragraph (d) of this section, a participant of the RCSSP will be liable to the United States for the amount that has been paid to or on behalf of the participant under the agreement if any of the following occurs: Liability under paragraph (b) of this section is in lieu of any service obligation arising under the agreement." We are eliminating the reference to paragraph (b) in the last sentence of this paragraph because liability applies to all of § 17.553. In addition, we are moving the last sentence of paragraph (b) to now be the first sentence of the paragraph for clarity. Paragraph (b) will now state that liability under this section is in lieu of any service obligation arising under the agreement. Except as provided in paragraph (d) of this section, a participant of the RCSSP will be liable to the United States for the amount that has been paid to or on behalf of the participant under the agreement if any of the following occurs. No other changes to the meaning of this paragraph are intended by this change.

Based on the rationale set forth in the **SUPPLEMENTARY INFORMATION** to the proposed rule and in this final rule, VA is adopting the proposed rule with the technical changes discussed in this rule.

Executive Orders 12866 and 13563

Executive Orders 12866 and 13563 direct agencies to assess the costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, and other advantages; distributive impacts; and equity). Executive Order 13563 (Improving Regulation and Regulatory Review) emphasizes the importance of quantifying both costs and benefits, reducing costs, harmonizing rules, and promoting flexibility. The Office of Information and Regulatory Affairs has determined that this rule is not a significant regulatory action under Executive Order 12866. The Regulatory Impact Analysis associated with this rulemaking can be found as a supporting document at www.regulations.gov.

Regulatory Flexibility Act

The Secretary hereby certifies that this final rule will not have a significant economic impact on a substantial number of small entities as they are defined in the Regulatory Flexibility Act (5 U.S.C. 601–612). The RCSSP will solely be operated and administered within VA. Therefore, pursuant to 5 U.S.C. 605(b), the initial and final regulatory flexibility analysis requirements of 5 U.S.C. 603 and 604 do not apply.

Unfunded Mandates

The Unfunded Mandates Reform Act of 1995 requires, at 2 U.S.C. 1532, that agencies prepare an assessment of anticipated costs and benefits before issuing any rule that may result in the expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of \$100 million or more (adjusted annually for inflation) in any one year. This final rule would have no such effect on State, local, and tribal governments, or on the private sector.

Paperwork Reduction Act (PRA)

The Paperwork Reduction Act of 1995 (44 U.S.C. 3507(d)) requires that VA consider the impact of paperwork and other information collection burdens imposed on the public. According to the 1995 amendments to the Paperwork Reduction Act (5 CFR 1320.8(b)(2)(vi)), an agency may not collect or sponsor the collection of information, nor may it impose an information collection requirement unless it displays a currently valid Office of Management and Budget (OMB) control number. This final rule includes provisions constituting a new collection of information under the Paperwork Reduction Act of 1995 that require approval by the OMB. Accordingly, under 44 U.S.C. 3507(d), VA has submitted a copy of this rulemaking action to OMB for review. OMB assigns control numbers to collections of information it approves. VA may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. Sections 17.548 and 17.551 contain a new collection of information. OMB has filed a comment on the information collection that was submitted in conjunction with the proposed rule in accordance with 5 CFR 1320.11(c) with a control number of 2900–0899. If OMB does not approve the collection of information as requested, VA will immediately remove the provisions containing a collection of information or

take such other action as is directed by OMB.

This information would be collected for applicants who wish to participate in the RCSSP. The information would also be collected for those individuals who are selected to participate in the RCSSP and who must sign an agreement between VA and the eligible individual. This agreement would hold the eligible individual accountable for upholding the terms and conditions of the agreement and alert the eligible individual of the consequences of a breach in the agreement.

VA estimates that there will be 50 applicants per year with five selected participants from the 50 applicants. The estimated average burden per response for applicants is three hours and for selected participants is 1.6 hours. VA estimates the annual cost to all respondents will be \$4,277 per year (158 burden hours × \$27.07 per hour). VA used the Bureau of Labor Statistics (BLS) median hourly wage for hourly wage for “all occupations” of \$27.07 per hour. This information is available at https://www.bls.gov/oes/current/oes_nat.htm#13-0000.

Assistance Listing

There are no Assistance Listing numbers and titles for this final rule.

Congressional Review Act

Pursuant to Subtitle E of the Small Business Regulatory Enforcement Fairness Act of 1996 (known as the Congressional Review Act) (5 U.S.C. 801 *et seq.*), the Office of Information and Regulatory Affairs designated this rule as not a major rule, as defined by 5 U.S.C. 804(2).

List of Subjects in 38 CFR Part 17

Administrative practice and procedure, Health care, Health facilities, Health professions, Scholarships and fellowships.

Signing Authority

Denis McDonough, Secretary of Veterans Affairs, approved this document on October 27, 2022, and authorized the undersigned to sign and submit the document to the Office of the Federal Register for publication electronically as an official document of the Department of Veterans Affairs.

Consuela Benjamin,

Regulations Development Coordinator, Office of Regulation Policy & Management, Office of General Counsel, Department of Veterans Affairs.

For the reasons stated in the preamble, the Department of Veterans Affairs amends 38 CFR part 17 as set forth below:

PART 17—MEDICAL

■ 1. The general authority citation for part 17 continues, and an entry for §§ 17.545 through 17.553 is added in numerical order, to read as follows:

Authority: 38 U.S.C. 501, and as noted in specific sections.

* * * * *

Sections 17.545 through 17.553 are also issued under 38 U.S.C. 7698, 7699, 7699A, and 7699B.

* * * * *

■ 2. Add an undesignated center heading and §§ 17.545 through 17.553 immediately following § 17.539 to read as follows:

Sec.

* * * * *

Readjustment Counseling Service Scholarship Program

17.545 Purpose.
17.547 Eligibility.
17.548 Application procedures.
17.549 Award procedures.
17.551 Agreement and obligated service.
17.553 Failure to comply with terms and conditions of agreement.

* * * * *

Readjustment Counseling Service Scholarship Program

§ 17.545 Purpose.

The purpose of §§ 17.545 through 17.553 is to establish the Readjustment Counseling Service Scholarship Program (RCSSP) as part of VA's Educational Assistance Program. For purposes of the RCSSP, the term Vet Center has the meaning given that term in 38 U.S.C. 1712A(h).

§ 17.547 Eligibility.

An individual is eligible to participate in the RCSSP if the individual meets the following requirements:

(a) Is accepted for enrollment or be currently enrolled on a full-time basis in a program of study at an accredited educational institution, school, or training program leading to a terminal doctorate degree in psychology, or a terminal masters degree in social work, marriage and family therapy, or mental health counseling that would meet the education requirements for appointment to a position in one of those fields under 38 U.S.C. 7402(b); and

(b) Enters into an agreement with the Secretary under § 17.551.

§ 17.548 Application procedures.

(a) *Availability.* VA will make awards under the RCSSP only when VA determines it is necessary to assist in alleviating shortages of psychologists, social workers, marriage and family therapists, or mental health counseling

professionals in Vet Centers. VA's determination of the number of RCSSP scholarships to be awarded in a fiscal year is subject to the availability of appropriations.

(b) *Application-general.* Each individual desiring a RCSSP scholarship must submit an accurate and complete application, including a signed written acceptance agreement.

(c) *VA's duties.* VA will notify applicants prior to acceptance in the RCSSP of the following information:

(1) A fair summary of the rights and liabilities of an individual whose application is approved by VA and whose acceptance agreement is consummated by VA; and

(2) A full description of the terms and conditions that apply to participation in the RCSSP and service in VA.

(The Office of Management and Budget has approved the information collection requirements in this section under control number 2900-0899.)

§ 17.549 Award procedures.

(a) *Priority.* In selecting individuals to participate in the RCSSP, VA will give priority to the following individuals:

(1) An individual who agrees to be employed by Vet Centers located in communities that are:

(i) Designated as a medically underserved population under section 330(b)(3) of the Public Health Service Act (42 U.S.C. 254b(b)(3)); and

(ii) In States with a per capita population of more than five percent veterans according to the National Center for Veterans Analysis and Statistics and the Bureau of the Census.

(2) A veteran.

(b) *Placement criteria.* When determining which Vet Center a scholarship recipient will be placed to carry out their service obligation, VA will consider the priority criteria in paragraph (a) of this section and the size and professional makeup of the current Vet Center staff to ensure that the Vet Center staff has health care professionals that are licensed to supervise participants of the RCSSP from the same health care profession as required by VA professional qualification standards and a requirement of some State licensure boards for some disciplines for each of the four professions.

(c) *Amount of funds.* VA will provide a scholarship to individuals who participate in the RCSSP to cover the actual costs of such individuals obtaining a terminal degree in psychology, social work, marriage and family therapy, or professional mental health counseling for a maximum of two years. If a participant completes their

terminal degree in less than two years, the period of obligated service remains unchanged.

(1) Social work, marriage and family therapy, and professional mental health counseling are master level programs that require approximately a two-year period for achieving the terminal degree. VA will fund RCSSP social work, marriage and family therapy, and professional mental health counseling participants for a maximum of two years.

(2) Psychology is a doctoral level program requiring approximately five years for completion of the terminal academic degree. In addition, psychology graduates are required to undergo a one-year internship at either an American Psychological Association (APA) or Canadian Psychological Association (CPA) accredited internship program prior to qualifying for full time VA employment. VA will fund psychology participants for the last two years of their five-year academic training to obtain a terminal doctorate degree. VA will not provide funding for the one-year APA or CPA internship under the RCSSP.

(d) *Payment of funds.* All such payments to scholarship participants are exempt from Federal taxation. The payments will consist of the actual cost of:

(1) Tuition and required fees;

(2) Other educational expenses, including books and laboratory equipment; and

(3) A monthly stipend, for the duration of the scholarship award. The Secretary may determine the amount of the stipend paid to participants, but that amount may not exceed the maximum amount provided for in 38 U.S.C. 7613(b).

§ 17.551 Agreement and obligated service.

(a) *Agreement.* Each participant who accepts funds from the RCSSP will enter into an agreement with VA where the participant agrees to the following:

(1) Maintain enrollment, attendance, and an acceptable level of academic standing as defined by the school;

(2) Obtain a terminal degree in psychology, social work, marriage and family therapy, or professional mental health counseling; and

(3) Be employed as a full-time VA employee at a Vet Center for a period of six-years as a psychologist, social worker, marriage and family therapist, or professional mental health counselor following the completion of such program of study.

(4) Psychologists must complete a one-year internship at either an American Psychological Association

(APA) or Canadian Psychological Association (CPA) accredited program. Obtaining an APA or CPA accredited internship requires that an individual participate in the Association of Psychology Postdoctoral and Internship Centers (APPIC) process. If a scholarship participant does not participate in an APA or CPA accredited internship, they are in breach of their agreement.

(b) *Obligated service—(1)*

Determination of service

commencement date. VA will notify the participant of the commencement date of the period of obligated service no later than 60 days before such date.

(2) *Commencement date of obligated service—(i) General.* A participant's period of obligated service will begin on the date the participant begins full-time permanent employment at a Vet Center as a psychologist, social worker, marriage and family therapist, or professional mental health counselor, but no later than 180 days after the date that the participant completes a terminal degree in one of the identified disciplines. Psychology participants will commence their period of obligated service no later than 180 days after completion of their one-year APA or CPA internship, which requires completion of all academic requirements to obtain a terminal doctorate degree.

(ii) *Independent practice.* Upon receipt of the terminal degree, participants will enter VA employment at the entry level until full licensure at the independent practice level has been attained. Independent practice licensure is a requirement for all scholarship participants. Non-licensed psychologists, social workers, marriage and family therapists, and professional mental health counselors are required to serve under the supervision of a licensed health care professional of their profession and must be independently licensed by a State within the time frame specified in VA qualification standards.

(iii) *VA monitoring of participants.* VA will actively assist and monitor participants to ensure State licenses are obtained in a minimal amount of time following graduation and the required period of supervision for their profession. If a participant fails to obtain their terminal degree or fails to obtain licensure in a State at the independent practice level no later than 180 days after the required period of supervision for their profession, the participant is considered to be in breach of the acceptance agreement.

(3) *Location and position of obligated service.* VA reserves the right to make

final decisions on the location and position of the obligated service. A participant who receives an RCSSP must be willing to relocate to another geographic location to carry out their service obligation in accordance with the participant's agreement. The requirement for participants to receive supervision from a licensed staff within their respective professions, as a condition for their own licensure, is a critical point for the consideration of the potential location of the obligated service.

(The Office of Management and Budget has approved the information collection requirements in this section under control number 2900-0899.)

§ 17.553 Failure to comply with terms and conditions of agreement.

(a) *Liquidated damages.* Except as provided in paragraph (b) of this section, a participant of the RCSSP who fails to accept payment or instructs the educational institution in which the participant is enrolled not to accept payment, in whole or in part, of a scholarship under the agreement entered into under § 17.551 will be liable to the United States for liquidated damages in the amount of \$1,500.

(b) *Liability during program of study.* Liability under this section is in lieu of any service obligation arising under the agreement. Except as provided in paragraph (d) of this section, a participant of the RCSSP will be liable to the United States for the amount that has been paid to or on behalf of the participant under the agreement if any of the following occurs:

(1) The participant fails to maintain an acceptable level of academic standing in the educational institution in which the participant is enrolled, as determined by the educational institution;

(2) The participant is dismissed from the educational institution for disciplinary reasons; or

(3) The participant voluntarily terminates the program of study in the educational institution before the completion of the program of study for which the RCSSP was awarded.

(c) *Liability during period of obligated service.* Except as provided in paragraph (d) of this section, if a participant of the RCSSP does not complete their period of obligated service, the United States will be entitled to recover from the participant an amount determined in accordance with the following formula: $A = 3\Phi(t - s/t)$, where:

(1) 'A' is the amount the United States is entitled to recover;

(2) 'Φ' is the sum of:

(i) The amounts paid under this subchapter to or on behalf of the participant; and

(ii) The interest on such amounts, which would be payable if at the time the amounts were paid they were loans bearing interest at the maximum legal prevailing rate, as determined by the Treasurer of the United States.

(3) 't' is the total number of months in the period of obligated service of the participant; and

(4) 's' is the number of months of such period served by the participant.

(d) *Limitation on liability for reductions-in-force.* Liability will not arise under paragraph (c) of this section if the participant fails to maintain employment as a VA employee due to a staffing adjustment.

(e) *Repayment period.* The participant will pay the amount of damages that the United States is entitled to recover under this section in full to the United States no later than one year after the date of the breach of the agreement.

[FR Doc. 2022-25093 Filed 11-21-22; 8:45 am]

BILLING CODE 8320-01-P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[EPA-R08-OAR-2022-0103; FRL-9624-02-R8]

Air Plan Approval; Colorado; Reg 3 NSR and APEN Updates

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: The Environmental Protection Agency (EPA) is finalizing approval of regulatory amendments submitted by the State of Colorado on May 13, 2020. The revisions make limited amendments to the State's New Source Review (NSR) and Air Pollution Emission Notices (APEN). The EPA is taking this action pursuant to the Clean Air Act (CAA).

DATES: This rule is effective on December 22, 2022.

ADDRESSES: The EPA has established a docket for this action under Docket ID No. EPA-R08-OAR-2022-0103. All documents in the docket are listed on the <http://www.regulations.gov> website. Although listed in the index, some information is not publicly available, e.g., CBI or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the internet and will be publicly

available only in hard copy form. Publicly available docket materials are available through <http://www.regulations.gov>, or please contact the person identified in the **FOR FURTHER INFORMATION CONTACT** section for additional availability information.

FOR FURTHER INFORMATION CONTACT:

Kevin Leone, Air and Radiation Division, EPA, Region 8, Mailcode 8ARD-IO, 1595 Wynkoop Street, Denver, Colorado 80202-1129, telephone number (303) 312-6227, email address leone.kevin@epa.gov.

SUPPLEMENTARY INFORMATION:

Throughout this document "we," "us," and "our" means the EPA.

I. Background

The background for this action is discussed in detail in our March 23, 2022 proposed rulemaking (87 FR 16439). In that document we proposed to approve revisions to Colorado's minor source NSR permitting program. Specifically, EPA proposed to approve revisions to Regulation Number 3 (Stationary Source Permitting and Air Pollution Emission Notice Requirements), including Part A (General Provisions Applicable to Reporting and Permitting), Part B (Construction Permits), and Part C (Operating Permits).

We invited comment on all aspects of our proposal and provided a 30-day comment period. The comment period ended on April 22, 2022. We received comments on our proposed rulemaking. The comments and our responses are listed below.

II. Response to Comments

On April 22, 2022, the EPA received comments from The Center for Biological Diversity, henceforth referred to as "commenter."

Comment: Commenter asserts, "EPA must disapprove the Colorado permitting program because it excludes emissions prior to operations such as drilling, fracking, and completion which may cause or contribute to violations of the NAAQS." In support of this assertion, commenter offers three arguments. First, Commenter states that EPA has not supported its approval of the State's revised definition of "Commencement of Operation" with modeling data to demonstrate that the revised definition will not cause or contribute to NAAQS violations. Commenter states that such modeling is required by EPA regulations to be included in State Implementation Plan (SIP) submittals. Second, Commenter states that available evidence indicates that "pre-production" emissions from

oil and gas facilities endanger the National Ambient Air Quality Standards (NAAQS). Commenter cites broadly to Colorado Air Mobile Monitoring Lab (CAMML) data, asserting that it shows that “activities which EPA proposes to approve into the SIP can endanger the NAAQS in violation of EPA’s regulations for minor source permitting programs.” Commenter also states that, “Preproduction emissions from oil and gas well pads are significant emitters of VOCs which contributes to ozone.” Finally, Commenter states that the revised definition of Commencement of Operation “excludes oil and gas pollution emitting activities such as drilling wells, ‘fracking’ wells, and completing wells.” Commenter argues, “40 CFR 51.160(e) requires states to justify the exclusion of any types of sources from review which is what the definition of commencement of operations does. But no justification has been provided here.”

Response: This SIP revision is approving limited rule revisions by Colorado that update the State’s permitting regulations to reflect consistency within the permitting program and with Colorado Statutes. This comment raises issues that extend beyond those presented by the two changes to Part A, Section I.B of Regulation 3, that EPA is approving. This includes the addition of clarifying language to the definition of “Commencement of Operation” at Section I.B.12 and a new definition of the term “Well Production Facility” at Section I.B.47. Prior to these changes, “Commencement of Operation” at any facility was defined to occur when the facility “first conduct[ed] the activity that it was designed and permitted for.” This part of the definition has not been revised and remains applicable to all facilities. With the two additions, however, “Commencement of Operation” at an oil and gas well production facility has been clarified and is now defined to occur on “the date any permanent production equipment is in use and product is consistently flowing to sales lines, gathering lines or storage tanks from the first producing well at the stationary source, but no later than end of well completion operations (including flowback).” These additions, while limited in scope, provide improved clarity for operators of oil and gas well production facilities and for the State as to the timelines for certain actions required in the minor NSR permit application process in Part B of Regulation 3. This includes establishing a clear date for assessing compliance

and impacts under Section III.B and a firm deadline for submitting notices and demonstrations under Section III.G. These regulatory changes are essentially procedural in nature and do not alter Colorado’s approach to issuing construction permits for emissions from facilities that have completed construction and begun operating.

This comment does not address the revisions described above and, instead, is based entirely on the part of the definition of “Commencement of Operation” that was not revised or addressed in the proposal. As described above, the State has retained its original, already approved definition and added language to clarify how that definition applies to oil and gas well production facilities. The limited revisions submitted for EPA’s review in this instance do not create a need for EPA to review the original definition language that has not been amended.

Commenter contends that EPA must use modeling data to support its conclusion that the revised definition does not cause or contribute to a violation of the NAAQS. However, Commenter bases this argument on an assertion that the revised definition “excludes oil and gas pollution emitting activities such as drilling wells, ‘fracking’ wells, and completing wells.” This comment conflates the revisions being approved today with the original definition that is not being revised. This comment seeks to have EPA and the State conduct air quality modeling for already approved SIP elements.

Because the two revisions being approved today serve only to clarify timelines for making assessments and deadlines for making submissions during the permit application process, the changes will have no impact on emissions from facilities and no impact on the NAAQS. The State has not revised the nature of the discussion of air quality data under its regulations in a way that requires EPA to reevaluate compliance with 40 CFR 51.160(f). Given the limited effect of the revision here, there was no need for Colorado to submit air quality modeling to support approval of these revisions.

Commenter also argues that EPA must disapprove the revisions being approved today because “pre-production” emissions from oil and gas facilities endanger the NAAQS. Again, this is outside the scope of the rulemaking because the Commenter does not tie this assertion to the actual revisions to Part A, Section I.B, but instead points to the existing part of the definition of “Commencement of Operation” that is not being revised. Commenter provides links to the CAMML dataset, but does

not explain how this data relates to EPA’s approval of the revisions being approved today. Contrary to the Commenter’s assertion, the State is not required to consider air quality data concerning already approved SIP elements when it revises other elements in a SIP and did not do so here. And, because the revisions being approved today are essentially procedural and only serve to establish timelines for conducting assessments or deadlines for making submissions during the permit application process, there is no air quality data available or that can be generated to assess the effect of the State’s revisions on the NAAQS for this action. Moreover, the provisions of Regulation 3 contain requirements for Stationary Source Permitting and Air Pollution Emission Notice Requirements. Drilling and fracking are not subject to regulation under Regulation 3. Instead, completion (pre-production flowback requirements) and production are regulated by Colorado’s Regulation 7, part D, which sources must be in compliance with immediately, upon commencement of operation.

Commenter also argues that the definition of “Commencement of Operation” excludes certain types of oil and gas well development activities and that the State must justify this exclusion. Commenter again relies on the existing part of the definition of “Commencement of Operation” that is not being modified or revised, rather than the revisions to Part A, Section I.B that EPA is approving today. As explained above, those additions serve to clarify certain timelines for the minor NSR permit application process for oil and gas well production facilities and have no impact on the State’s determination as to what facilities will be subject to review under the construction permit program. Because these revisions provide clarity on procedures, and do not by themselves exclude any types of sources from review, they do not create a need in this rulemaking for EPA to review whether unamended elements of the State’s rule meet the requirements in 40 CFR 51.160(e).

On the basis of the above arguments, Commenter states that EPA must disapprove the entire Colorado minor NSR permitting program. This assertion is incorrect. Under Section 110(l) of the CAA, “The Administrator shall not approve a revision to a plan if the revision would interfere with any applicable requirement concerning attainment and reasonable further progress (as defined in section 171), or any other applicable requirement of this

chapter.” This is captured in 40 CFR 51.105, which provides, “Revisions of a plan, or any portion thereof, will not be considered part of an applicable plan until such revisions have been approved by the Administrator in accordance with this part.” Even if the Commenter had identified deficiencies with the actual revisions being approved today, which they did not, the proper action for EPA would be to disapprove the revisions we are acting on in this rulemaking, not the entire Colorado minor NSR program. In this case, because the revisions to Part A, Section I.B of Regulation 3 serve only to clarify the timelines for certain actions required in the minor NSR permit application process in Part B of Regulation 3, there is sufficient basis to conclude that the revisions will not interfere with attainment, reasonable further progress, or any other applicable requirement of the CAA. EPA has made no changes to its proposed action in response to this comment.

Comment: Commenter states, “EPA must disapprove Colorado’s SIP submittal because Colorado cannot prevent the construction of a source authorized to pollute by a general permit even if the source will cause or contribute to a violation of a NAAQS or interfere [sic] with reasonable further progress.” In support of this comment, Commenter states that Part B, Section III.I.2.a authorizes a source to construct and operate once they have obtained a valid general construction permit. Commenter then argues that because Colorado’s GP10 version 10 is considered valid upon receipt of a complete APEN registration for a source, Section III.I.2.a allows a source to begin constructing and operating before the Division takes any action on a general permit for that source. Commenter explains that sources are not required to demonstrate that they will not cause or contribute to a violation of the NAAQS, that the Division does not require modeling for these sources, that there is no public comment period during which the public can submit modeling for these sources, and that when the Division does require modeling for sources obtaining individual construction permits, the Division uses significant impact levels (SILs) to allow sources to avoid cumulative modeling. Commenter states that because EPA has provided no evidence that allowing sources to construct and operate pursuant to a general construction permit will not cumulatively or individually cause or contribute to a NAAQS violation or interfere with reasonable further progress, EPA cannot approve this SIP submittal.

Commenter notes that Section 110(a)(2)(C) provides that a state minor source program must “include . . . regulation of the modification and construction of any stationary source within the areas covered by the plan as necessary to assure that [NAAQS] are achieved.” Commenter asserts that “EPA’s minor source permitting regulations require that the state minor source program must enable the permitting agency to reject any permit application if it will interfere with attainment,” citing to 40 CFR 51.160(a)–(b). Commenter further asserts that “this requires the prevention of construction” and that because Colorado allows a source to construct and operate under a general permit prior to Division review of the registration, EPA must disapprove the SIP submittal.

Finally, commenter asserts that Section III.I.2.a authorizes sources to commence construction and operations by obtaining a valid general construction permit without any opportunity for public notice and comment with regard to that source. Commenter asserts that the single public notice and comment period the State offers on a general permit is insufficient, and that EPA and the Division must ensure that all sources which obtain coverage under a general permit are subjected to public notice and a public comment period.

Response: Part B, Section III.I.2 of Regulation 3 provides that “[a] source shall not perform” the activities listed in Sections III.I.2.a through III.I.2.e without first obtaining a valid construction general permit. The State is revising Part B, Section III.I.2.a by removing the words “Commence construction” and replacing them with “Construct, operate.” Before the change, sources could not commence construction or modify any facility without a valid permit. After the change, sources cannot construct, operate or modify any facility without a valid permit. The effect of the change is to make the regulation textually consistent with Section 25–7–114.2 C.R.S., which provides that “No person shall construct or substantially alter any building, facility, structure, or installation . . . or commence operations of any of the same . . . without first obtaining or having a valid construction permit.”

Because the Division implemented its construction permit program to include operation with construction or modification, the change to the wording within this provision has no effect on the scope or NAAQS protection of the existing general permits program, or timing of when permit coverage under

the program is required. As such, the comment is unrelated to the revised language that EPA is approving today and does not demonstrate that EPA should not approve the submission addressed by EPA in this rulemaking.

In addition, EPA notes that the State’s general permit regulation includes provisions by which the State can prevent “construction or modification” of a source under a permit, as required by 40 CFR 51.160(b). This includes denying a permit under Section III.I.4, requiring a source to apply for and obtain an individual permit under Section III.I.3.c.(i), or revoking or terminating a permit under Section III.I.3.a.

III. Final Action

The EPA is taking final action to approve the repealing and addition of new and revised rules to Regulation 3 that were submitted by the State of Colorado on May 13, 2020. Specifically, the EPA is approving the following revisions: Regulation Number 3, Part A: I. (Applicability)—I.B.12; I.B.47; Regulation Number 3, Part A: II (Air Pollution Emission Notice (APEN) Requirements—I.I.A.1; II.A.2; II.A.2(a); II.D.1.III; II.D.1.uuu; II.D.1.zzz; Regulation Number 3, Part B: II. (General Requirements for Construction Permits)—II.A.1; II.B; II.D.7.; Regulation Number 3, Part B: III. (Construction Permit Review Procedures)—III.B.1; III.B.2; and III.G.1.a., III.I.2(a).

IV. Incorporation by Reference

In this document, the EPA is finalizing regulatory text that includes incorporation by reference. In accordance with requirements of 1 CFR 51.5, the EPA is finalizing the incorporation by reference of the State of Colorado’s revisions to regulations for its minor source NSR permitting program into the SIP as described in section III of this preamble. The EPA will continue to make these materials generally available through www.regulations.gov and at the EPA Region 8 Office (please contact the person identified in the **FOR FURTHER INFORMATION CONTACT** section of this preamble for more information). Therefore, these materials have been approved by the EPA for inclusion in the State implementation plan, have been incorporated by reference by the EPA into that plan, are fully federally enforceable under sections 110 and 113 of the CAA as of the effective date of the final rulemaking of the EPA’s approval, and will be incorporated by reference in the next update to the SIP compilation.¹

¹ 62 FR 27968 (May 22, 1997).

V. Statutory and Executive Order Reviews

Under the CAA, the Administrator is required to approve a SIP submission that complies with the provisions of the Act and applicable Federal regulations. 42 U.S.C. 7410(k); 40 CFR 52.02(a). Thus, in reviewing SIP submissions, the EPA's role is to approve state choices, provided that they meet the criteria of the CAA. Accordingly, this action merely approves state law as meeting Federal requirements and does not impose additional requirements beyond those imposed by state law. For that reason, this action:

- Is not a "significant regulatory action" subject to review by the Office of Management and Budget under Executive Orders 12866 (58 FR 51735, October 4, 1993) and 13563 (76 FR 3821, January 21, 2011);
- Does not impose an information collection burden under the provisions of the Paperwork Reduction Act (44 U.S.C. 3501 *et seq.*);
- Is certified as not having a significant economic impact on a substantial number of small entities under the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*);
- Does not contain any unfunded mandate or significantly or uniquely affect small governments, described in the Unfunded Mandates Reform Act of 1995 (Pub. L. 104-4);
- Does not have Federalism implications as specified in Executive Order 13132 (64 FR 43255, August 10, 1999);
- Is not an economically significant regulatory action based on health or safety risks subject to Executive Order 13045 (62 FR 19885, April 23, 1997);
- Is not a significant regulatory action subject to Executive Order 13211 (66 FR 28355, May 22, 2001);
- Is not subject to requirements of section 12(d) of the National Technology Transfer and Advancement Act of 1995 (15 U.S.C. 272 note) because

application of those requirements would be inconsistent with the CAA; and

- Does not provide EPA with the discretionary authority to address, as appropriate, disproportionate human health or environmental effects, using practicable and legally permissible methods, under Executive Order 12898 (59 FR 7629, February 16, 1994).

In addition, the SIP is not approved to apply on any Indian reservation land or in any other area where EPA or an Indian tribe has demonstrated that a tribe has jurisdiction. In those areas of Indian country, the rule does not have tribal implications and will not impose substantial direct costs on tribal governments or preempt tribal law as specified by Executive Order 13175 (65 FR 67249, November 9, 2000).

The Congressional Review Act, 5 U.S.C. 801 *et seq.*, as added by the Small Business Regulatory Enforcement Fairness Act of 1996, generally provides that before a rule may take effect, the agency promulgating the rule must submit a rule report, which includes a copy of the rule, to each House of the Congress and to the Comptroller General of the United States. EPA will submit a report containing this action and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of the rule in the **Federal Register**. A major rule cannot take effect until 60 days after it is published in the **Federal Register**. This action is not a "major rule" as defined by 5 U.S.C. 804(2).

Under section 307(b)(1) of the Clean Air Act, petitions for judicial review of this action must be filed in the United States Court of Appeals for the appropriate circuit by January 23, 2023. Filing a petition for reconsideration by the Administrator of this final rule does not affect the finality of this action for the purposes of judicial review nor does it extend the time within which a petition for judicial review may be filed, and shall not postpone the effectiveness

of such rule or action. This action may not be challenged later in proceedings to enforce its requirements (see section 307(b)(2)).

List of Subjects in 40 CFR Part 52

Environmental protection, Air pollution control, Carbon monoxide, Greenhouse gases, Incorporation by reference, Intergovernmental relations, Lead, Nitrogen dioxide, Ozone, Particulate matter, Reporting and recordkeeping requirements, Sulfur oxides, Volatile organic compounds.

Dated: November 8, 2022.

K.C. Becker,

Regional Administrator, Region 8.

For the reasons set forth in the preamble, 40 CFR part 52 is amended as follows:

PART 52—APPROVAL AND PROMULGATION OF IMPLEMENTATION PLANS

- 1. The authority for citation for part 52 continues to read as follows:

Authority: 42 U.S.C. 7401 *et seq.*

Subpart G—Colorado

- 2. In § 52.320, in the table in paragraph (c):

■ a. Revise, under the center heading "5 CCR 1001–05, Regulation Number 3, Part A, Concerning General Provisions Applicable to Reporting and Permitting" the entries: "I. Applicability" and "II. Air Pollution Emission Notice (APEN) Requirements".

■ b. Revise, under the center heading "5 CCR 1001–05, Regulation Number 3, Part B, Concerning Construction Permits the entries: "II. General Requirements for Construction Permits" and "III. Construction Permit Review Procedures".

The revisions read as follows:

§ 52.320 Identification of plan.

* * * * *

(c) * * *

Title	State effective date	EPA effective date	Final rule citation/date	Comments
* * *	* * *	* * *	* * *	* * *
5 CCR 1001–05, Regulation Number 3, Part A, Concerning General Provisions Applicable to Reporting and Permitting				
I. Applicability	2/14/2020	12/22/2022	[insert Federal Register citation], 11/22/2022.	
II. Air Pollution Emission Notice (APEN) Requirements.	2/14/2020	12/22/2022	[insert Federal Register citation], 11/22/2022.	

Title	State effective date	EPA effective date	Final rule citation/date	Comments
*	*	*	*	*
5 CCR 1001–05, Regulation Number 3, Part B, Concerning Construction Permits				
II. General Requirements for Construction Permits.	2/14/2020	12/22/2022	[insert Federal Register citation], 11/22/2022.	*
III. Construction Permit Review Procedures	2/14/2020	12/22/2022	[insert Federal Register citation], 11/22/2022.	*
*	*	*	*	*

* * * * *

[FR Doc. 2022–24858 Filed 11–21–22; 8:45 am]

BILLING CODE 6560–50–P

DEPARTMENT OF VETERANS AFFAIRS

48 CFR Parts 819 and 852

RIN 2900–AR06

VA Acquisition Regulation: Acquisition Planning; Required Sources of Supplies and Services; Market Research; and Small Business Programs; Correction

AGENCY: Department of Veterans Affairs.
ACTION: Correcting amendment.

SUMMARY: The Department of Veterans Affairs (VA) is correcting the VA Acquisition Regulation (VAAR) concerning Small Business Programs and Solicitation Provisions and Contract Clauses. This correction addresses three minor administrative typos involving references to the VAAR in the regulations.

DATES: This correction is effective November 22, 2022.

FOR FURTHER INFORMATION CONTACT: Ms. Glacia Holbert, Senior Procurement Analyst, Procurement Policy and Warrant Management Service, 003A2A, 810 Vermont Avenue NW, Washington, DC 20420, (202) 697–3614. (This is not a toll-free number.)

SUPPLEMENTARY INFORMATION: VA is correcting its regulations that published in the final rule “VA Acquisition Regulation: Acquisition Planning; Required Sources of Supplies and Services; Market Research; and Small Business Programs,” which published October 18, 2022, in the rule document in the **Federal Register** at 87 FR 62999.

List of Subjects

48 CFR Part 819

Administrative practice and procedure, Government procurement,

Reporting and recordkeeping requirements, Small business, Veterans.

48 CFR Part 852

Government procurement, Reporting and recordkeeping requirements.

Accordingly, 48 CFR parts 819 and 852 are corrected by making the following correcting amendments:

PART 819—SMALL BUSINESS PROGRAMS

- 1. The authority citation for part 819 continues to read as follows:

Authority: 15 U.S.C. 631, *et seq.*; 15 U.S.C. 637(d)(4)(E); 38 U.S.C. 8127–8128; 40 U.S.C. 121(c); 41 U.S.C. 1121(c)(3); 41 U.S.C. 1303; 41 U.S.C. 1702; and 48 CFR 1.301 through 1.304.

819.7002 [Amended]

- 2. In section 819.7002, amend the second sentence by removing “(see 817.502)” and adding “(see 817.501)” in its place.

PART 852—SOLICITATION PROVISIONS AND CONTRACT CLAUSES

- 3. The authority citation for part 852 continues to read as follows:

Authority: 38 U.S.C. 8127–8128 and 8151–8153; 40 U.S.C. 121(c); 41 U.S.C. 1121(c)(3); 41 U.S.C. 1303; 41 U.S.C. 1702; and 48 CFR 1.301 through 1.304.

852.219–73 [Amended]

- 4. In section 852.219–73, amend paragraph (a)(1)(i) by removing “802.201” and adding “802.101” in its place.

852.219–74 [Amended]

- 5. In section 852.219–74, amend paragraph (g) by removing “802.10” and adding “802.101” in its place.

Approved: November 15, 2022.

Consuela Benjamin,
Regulations Development Coordinator, Office of Regulation Policy & Management, Office of the General Counsel, Department of Veterans Affairs.

[FR Doc. 2022–25238 Filed 11–21–22; 8:45 am]

BILLING CODE 8320–01–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Part 660

[RTID 0648–XC119]

Fisheries Off West Coast States; West Coast Salmon Fisheries; Amendment 23 to the Pacific Coast Salmon Fishery Management Plan

AGENCY: National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce.

ACTION: Notice of agency decision.

SUMMARY: NMFS announces the approval of Amendment 23 to the Pacific Coast Salmon Fishery Management Plan (Salmon FMP). Amendment 23 amends the Salmon FMP’s current harvest control rule (HCR) for the Southern Oregon/Northern California Coast (SONCC) Coho Salmon Evolutionarily Significant Unit (ESU).

DATES: The amendment was approved on November 10, 2022.

ADDRESSES: The amended Salmon FMP is available on the Pacific Fishery Management Council’s (Council) website (www.pcouncil.org). The final National Environmental Policy Act (NEPA) environmental assessment (EA) evaluating this action is available on the NMFS website at <https://www.fisheries.noaa.gov/west-coast/laws-and-policies/west-coast-salmon-harvest-nepa-documents>.

FOR FURTHER INFORMATION CONTACT:
Shannon Penna at 562–980–4239.

SUPPLEMENTARY INFORMATION:

Background

The ocean salmon fisheries in the exclusive economic zone (EEZ) (3–200 nautical miles; 5.6–370.4 kilometers) seaward of Washington, Oregon, and California are managed under the Salmon FMP. The Magnuson-Stevens Fishery Conservation and Management Act (MSA) requires that each regional fishery management council submit any fishery management plan (FMP) or plan amendment it prepares to NMFS for review and approval, disapproval, or partial approval by the Secretary of Commerce (Secretary) (MSA 304(a)). The MSA also requires that NMFS, upon receiving an FMP or plan amendment, immediately publish a notice that the FMP or plan amendment is available for public review and comment.

The Notice of Availability (NOA) for Amendment 23 was published in the **Federal Register** on August 18, 2022 (87 FR 50824), with a 60-day comment period that ended on October 17, 2022. In the NOA, NMFS also announced that a draft EA analyzing the environmental impacts of the actions implemented under Amendment 23 was available for public review and comments by October 3, 2022. NMFS summarized and responded to comments in the final EA, and under Comments and Responses, below.

NMFS completed a biological opinion under section 7 of the ESA on the implementation of the Salmon FMP, including Amendment 23, and determined that this action is not likely to jeopardize the continued existence of any endangered or threatened species under the jurisdiction of NMFS (NMFS

Consultation Number: WCRO–2021–03260; biological opinion signed April 28, 2022).

NMFS determined that Amendment 23 is consistent with the MSA and other applicable laws, and the Secretary of Commerce approved Amendment 23 on November 10, 2022. The August 18, 2022 NOA contains additional information on this action. Amendment 23 will be implemented through the annual salmon management measures; no changes to existing Federal regulations are necessary.

Amendment 23 will replace the current HCR with two new HCRs. The first will limit total fishery exploitation rates (ERs) on each of five individual representative population units within the SONCC coho salmon ESU to 15 percent annually, except for the Trinity River population (represented by the Upper Trinity River, Lower Trinity River, and South Fork Trinity River populations). The second HCR will limit the total ER on the Trinity River population unit to 16 percent. Both HCRs account for all ocean and inland sources of fishery mortality annually and include landed and non-landed mortality of age-3 adult SONCC coho salmon.

During its annual salmon preseason planning process for developing recommended annual management measures governing ocean salmon fisheries, the Council will evaluate ocean salmon fisheries using the coho salmon Fishery Regulation Assessment Model (FRAM) so that, when combined with estimated freshwater impacts, the preseason projected total ERs will not exceed the adopted HCRs. The estimated freshwater impacts will be determined using projections provided by co-managing agencies (*i.e.*, the Oregon Department of Fish and

Wildlife, Yurok Tribe, Hoopa Valley Tribe, or California Department of Fish and Wildlife). Postseason ERs will be estimated for each year once postseason harvest and abundance estimates become available. Coho salmon-directed salmon fisheries and retention of coho salmon in Chinook salmon-directed salmon fisheries will remain prohibited in the EEZ seaward of California. Annual salmon management measures implemented consistent with Amendment 23 will be applied in concert with measures designed to meet other requirements of the FMP including conservation objectives and annual catch limits for specific salmon stocks and stock complexes.

Comments and Responses

NMFS received four comments during the public comment period. Three comments were from private citizens and the fourth comment was a letter from the United States (U.S.) Environmental Protection Agency (EPA). One comment from private citizens was in support of Amendment 23 and two comments were not relevant to the scope of Amendment 23. The EPA specifically addresses the draft EA by providing recommendations for NMFS to clearly document tribal engagement and to clearly describe the final project in the final EA. NMFS incorporated the recommendations from the comments received from the EPA into the final EA.

Authority: 16 U.S.C. 1801 *et seq.*

Dated: November 16, 2022.

Samuel D. Rauch, III,

*Deputy Assistant Administrator for
Regulatory Programs, National Marine
Fisheries Service.*

[FR Doc. 2022–25328 Filed 11–21–22; 8:45 am]

BILLING CODE 3510–22–P

Proposed Rules

Federal Register

Vol. 87, No. 224

Tuesday, November 22, 2022

This section of the FEDERAL REGISTER contains notices to the public of the proposed issuance of rules and regulations. The purpose of these notices is to give interested persons an opportunity to participate in the rule making prior to the adoption of the final rules.

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA-2022-1484; Project Identifier MCAI-2022-00897-G]

RIN 2120-AA64

Airworthiness Directives; Schempp-Hirth Flugzeugbau GmbH Gliders

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of proposed rulemaking (NPRM).

SUMMARY: The FAA proposes to adopt a new airworthiness directive (AD) for all Schempp-Hirth Flugzeugbau GmbH Model Duo Discus and Duo Discus T gliders. This proposed AD results from mandatory continuing airworthiness information (MCAI) originated by an aviation authority of another country to identify and correct an unsafe condition on an aviation product. The MCAI identifies the unsafe condition as the airbrake becoming blocked or jammed in an extended position during high airspeed due to an incorrect adjustment on the airbrake system. This proposed AD would require repetitively inspecting the airbrake system and corrective action as necessary. The FAA is proposing this AD to address the unsafe condition on these products.

DATES: The FAA must receive comments on this NPRM by January 6, 2023.

ADDRESSES: You may send comments, using the procedures found in 14 CFR 11.43 and 11.45, by any of the following methods:

- *Federal eRulemaking Portal:* Go to [regulations.gov](https://www.regulations.gov). Follow the instructions for submitting comments.

- *Fax:* (202) 493-2251.

- *Mail:* U.S. Department of Transportation, Docket Operations, M-30, West Building Ground Floor, Room W12-140, 1200 New Jersey Avenue SE, Washington, DC 20590.

- *Hand Delivery:* Deliver to Mail address above between 9 a.m. and 5

p.m., Monday through Friday, except Federal holidays.

AD Docket: You may examine the AD docket at [regulations.gov](https://www.regulations.gov) under Docket No. FAA-2022-1484; or in person at Docket Operations between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The AD docket contains this NPRM, the MCAI, any comments received, and other information. The street address for Docket Operations is listed above.

Material Incorporated by Reference:

- For service information identified in this NPRM, contact Schempp-Hirth Flugzeugbau GmbH, Krehenstrasse 25, Kirchheim unter Teck, Germany; phone: +49 7021 7298-0; email: info@schempp-hirth.com; website: [schempp-hirth.com](https://www.schempp-hirth.com).

- You may view this service information at the FAA, Airworthiness Products Section, Operational Safety Branch, 901 Locust, Kansas City, MO 64106. For information on the availability of this material at the FAA, call (817) 222-5110.

FOR FURTHER INFORMATION CONTACT: Jim Rutherford, Aviation Safety Engineer, General Aviation & Rotorcraft Section, International Validation Branch, FAA, 901 Locust, Room 301, Kansas City, MO 64106; phone: (816) 329-4165; email: jim.rutherford@faa.gov.

SUPPLEMENTARY INFORMATION:

Comments Invited

The FAA invites you to send any written relevant data, views, or arguments about this proposal. Send your comments to an address listed under **ADDRESSES**. Include "Docket No. FAA-2022-1484; Project Identifier MCAI-2022-00897-G" at the beginning of your comments. The most helpful comments reference a specific portion of the proposal, explain the reason for any recommended change, and include supporting data. The FAA will consider all comments received by the closing date and may amend this proposal because of those comments.

Except for Confidential Business Information (CBI) as described in the following paragraph, and other information as described in 14 CFR 11.35, the FAA will post all comments received, without change, to [regulations.gov](https://www.regulations.gov), including any personal information you provide. The agency will also post a report summarizing each substantive verbal contact received about this NPRM.

Confidential Business Information

CBI is commercial or financial information that is both customarily and actually treated as private by its owner. Under the Freedom of Information Act (FOIA) (5 U.S.C. 552), CBI is exempt from public disclosure. If your comments responsive to this NPRM contain commercial or financial information that is customarily treated as private, that you actually treat as private, and that is relevant or responsive to this NPRM, it is important that you clearly designate the submitted comments as CBI. Please mark each page of your submission containing CBI as "PROPIN." The FAA will treat such marked submissions as confidential under the FOIA, and they will not be placed in the public docket of this NPRM. Submissions containing CBI should be sent to Jim Rutherford, Aviation Safety Engineer, General Aviation & Rotorcraft Section, International Validation Branch, FAA, 901 Locust, Room 301, Kansas City, MO 64106. Any commentary that the FAA receives which is not specifically designated as CBI will be placed in the public docket for this rulemaking.

Background

The European Union Aviation Safety Agency (EASA), which is the Technical Agent for the Member States of the European Union, has issued EASA AD 2022-0138, dated July 7, 2022 (referred to after this as "the MCAI"), to correct an unsafe condition on all Schempp-Hirth Flugzeugbau GmbH Model Duo Discus, Duo Discus C, and Duo Discus T gliders. The MCAI states that an instance of the airbrake becoming blocked or jammed in an extended position during high airspeed on a Duo Discus glider occurred due to an incorrect adjustment on the airbrake system. A review of the manufacturer's maintenance manual revealed more maintenance information is needed to maintain the airbrake system in a serviceable condition. Accordingly, the MCAI requires repetitive inspections of the airbrake system and, depending on findings, accomplishing corrective actions in accordance with existing Schempp-Hirth Flugzeugbau GmbH maintenance instructions or instructions received by contacting Schempp-Hirth Flugzeugbau GmbH.

This condition, if not detected and corrected, could lead to blockage or

jamming of the airbrake and result in reduced control of the glider.

You may examine the MCAI in the AD docket at [regulations.gov](https://www.regulations.gov) under Docket No. FAA–2022–1484.

Related Service Information Under 14 CFR Part 51

The FAA reviewed Schempp-Hirth Flugzeugbau GmbH Maintenance Information SHK–M–01–22 for the Duo Discus and Duo Discus T airbrake system, dated January 26, 2022, which specifies procedures for inspecting and adjusting the airbrake system.

This service information is reasonably available because the interested parties have access to it through their normal course of business or by the means identified in **ADDRESSES**.

FAA's Determination

These products have been approved by the aviation authority of another country and are approved for operation in the United States. Pursuant to the FAA's bilateral agreement with this State of Design Authority, it has notified the FAA of the unsafe condition

described in the MCAI and service information described above. The FAA is issuing this NPRM after determining that the unsafe condition described previously is likely to exist or develop on other products of these same type designs.

Proposed AD Requirements in This NPRM

This proposed AD would require accomplishing the actions specified in the MCAI, except as discussed under "Differences Between this Proposed AD and the MCAI."

Differences Between This Proposed AD and the MCAI

The MCAI applies to Schempp-Hirth Flugzeugbau GmbH Model Duo Discus C gliders, and this proposed AD does not because this model does not have an FAA type certificate.

The MCAI requires accomplishing applicable corrective action in accordance with approved Schempp-Hirth Flugzeugbau GmbH maintenance instructions or contacting Schempp-

Hirth Flugzeugbau GmbH for approved instructions and accomplishing those instructions accordingly. This proposed AD would require adjusting the airbrake system in accordance with a method approved by the FAA; EASA; or Schempp-Hirth Flugzeugbau GmbH's Design Organization Approval (DOA). If approved by the DOA, the approval must include the DOA-authorized signature.

The MCAI references incorporating maintenance tasks into the Schempp-Hirth Aircraft Maintenance Program (AMP) to ensure accomplishment of the tasks required in the MCAI. Because the AMP is not required by FAA regulations for U.S. operators of the affected gliders, the proposed AD does not reference this and the actions are contained within the proposed AD.

Costs of Compliance

The FAA estimates that this AD, if adopted as proposed, would affect 32 gliders of U.S. registry.

The FAA estimates the following costs to comply with this proposed AD:

ESTIMATED COSTS

Action	Labor cost	Parts cost	Cost per product	Cost on U.S. operators
Inspect airbrake system	2 work-hours × \$85 per hour = \$170	Not applicable	\$170 per inspection cycle.	\$5,440 per inspection cycle.

The FAA estimates the following costs to do any necessary actions that

would be required based on the results of the proposed inspection. The agency

has no way of determining the number of gliders that might need this action:

ON-CONDITION COSTS

Action	Labor cost	Parts cost	Cost per product
Adjust airbrake system	4 work-hours × \$85 per hour = \$340	\$200	\$540

Authority for This Rulemaking

Title 49 of the United States Code specifies the FAA's authority to issue rules on aviation safety. Subtitle I, section 106, describes the authority of the FAA Administrator. Subtitle VII: Aviation Programs, describes in more detail the scope of the Agency's authority.

The FAA is issuing this rulemaking under the authority described in Subtitle VII, Part A, Subpart III, Section 44701: General requirements. Under that section, Congress charges the FAA with promoting safe flight of civil aircraft in air commerce by prescribing regulations for practices, methods, and procedures the Administrator finds necessary for safety in air commerce.

This regulation is within the scope of that authority because it addresses an unsafe condition that is likely to exist or develop on products identified in this rulemaking action.

Regulatory Findings

The FAA determined that this proposed AD would not have federalism implications under Executive Order 13132. This proposed AD would not have a substantial direct effect on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government.

For the reasons discussed above, I certify this proposed regulation:

(1) Is not a "significant regulatory action" under Executive Order 12866,

(2) Would not affect intrastate aviation in Alaska, and

(3) Would not have a significant economic impact, positive or negative, on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

List of Subjects in 14 CFR Part 39

Air transportation, Aircraft, Aviation safety, Incorporation by reference, Safety.

The Proposed Amendment

Accordingly, under the authority delegated to me by the Administrator, the FAA proposes to amend 14 CFR part 39 as follows:

PART 39—AIRWORTHINESS DIRECTIVES

- 1. The authority citation for part 39 continues to read as follows:

Authority: 49 U.S.C. 106(g), 40113, 44701.

§ 39.13 [Amended]

- 2. The FAA amends § 39.13 by adding the following new airworthiness directive:

Schempp-Hirth Flugzeugbau GmbH: Docket No. FAA–2022–1484; Project Identifier MCAI–2022–00897–G.

(a) Comments Due Date

The FAA must receive comments on this airworthiness directive (AD) by January 6, 2023.

(b) Affected ADs

None.

(c) Applicability

This AD applies to Schempp-Hirth Flugzeugbau GmbH (Schempp-Hirth) Model Duo Discus and Duo Discus T gliders, all serial numbers, certificated in any category.

(d) Subject

Joint Aircraft System Component (JASC) Code 2760, Drag Control System.

(e) Unsafe Condition

This AD was prompted by mandatory continuing airworthiness information (MCAI) originated by an aviation authority of another country to identify and correct an unsafe condition on an aviation product. The MCAI identifies the unsafe condition as blocking or jamming of the airbrake. The FAA is issuing this AD to detect and correct such blockage or jamming of the airbrake system. The unsafe condition, if not addressed, could result in reduced control of the glider.

(f) Compliance

Comply with this AD within the compliance times specified, unless already done.

(g) Actions

(1) Within 12 months after the effective date of this AD and thereafter at intervals not to exceed 12 months, inspect the airbrake system for smooth operation, for sufficient airbrake panel overlap, and for proper cockpit control adjustment in accordance with Section I, and either II or III, depending on your glider configuration, of Schempp-Hirth Flugzeugbau GmbH Maintenance Information SHK–M–01–22 for the Duo Discus and Duo Discus T airbrake system, dated January 26, 2022.

Note 1 to paragraph (g)(1): Schempp-Hirth Flugzeugbau GmbH Technical Note 396–21, dated January 26, 2022; and Schempp-Hirth Flugzeugbau GmbH Technical Note 890–17, dated January 26, 2022, contain information related to this subject.

(2) If, during any inspection as required by paragraph (g)(1) of this AD, any part of the airbrake system is not properly adjusted, before further flight, adjust the airbrake system in accordance with a method

approved by the FAA; the European Union Aviation Safety Agency (EASA); or Schempp-Hirth's Design Organization Approval (DOA). If approved by the DOA, the approval must include the DOA-authorized signature.

(h) Alternative Methods of Compliance (AMOCs)

The Manager, International Validation Branch, FAA, has the authority to approve AMOCs for this AD, if requested using the procedures found in § 39.19. In accordance with § 39.19, send your request to your principal inspector or local Flight Standards District Office, as appropriate. If sending information directly to the manager of the International Validation Branch, send it to the attention of the person identified in paragraph (i)(2) of this AD or email to: 9-AVS-AIR-730-AMOC@faa.gov. If mailing information, also submit information by email.

(i) Additional Information

(1) Refer to EASA AD 2022–0138, dated July 7, 2022, for related information. This EASA AD may be found in the AD docket at www.regulations.gov under Docket No. FAA–2022–1484.

(2) For more information about this AD, contact Jim Rutherford, Aviation Safety Engineer, General Aviation & Rotorcraft Section, International Validation Branch, FAA, 901 Locust, Room 301, Kansas City, MO 64106; phone: (816) 329–4165; email: jim.rutherford@faa.gov.

(3) Service information identified in this AD that is not incorporated by reference is available at the addresses specified in paragraphs (j)(3) and (4) of this AD.

(j) Material Incorporated by Reference

(1) The Director of the Federal Register approved the incorporation by reference of the service information listed in this paragraph under 5 U.S.C. 552(a) and 1 CFR part 51.

(2) You must use this service information as applicable to do the actions required by this AD, unless the AD specifies otherwise.

(i) Schempp-Hirth Flugzeugbau GmbH Maintenance Information SHK–M–01–22 for the Duo Discus and Duo Discus T airbrake system, dated January 26, 2022.

(ii) [Reserved]

(3) For service information identified in this AD, contact Schempp-Hirth Flugzeugbau GmbH, Krehenstrasse 25, Kirchheim unter Teck, Germany; phone: +49 7021 7298–0; email: info@schempp-hirth.com; website: schempp-hirth.com.

(4) You may view this service information at the FAA, Airworthiness Products Section, Operational Safety Branch, 901 Locust, Kansas City, MO 64106. For information on the availability of this material at the FAA, call (817) 222–5110.

(5) You may view this service information that is incorporated by reference at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, email: fr.inspection@nara.gov, or go to: www.archives.gov/federal-register/cfr/ibr-locations.html.

Issued on November 16, 2022.

Christina Underwood,

Acting Director, Compliance & Airworthiness Division, Aircraft Certification Service.

[FR Doc. 2022–25367 Filed 11–21–22; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 71

[Docket No. FAA–2022–1395 Airspace
Docket No. 22–ACE–10]

RIN 2120–AA66

Proposed Amendment of Multiple Air Traffic Service (ATS) Routes and Revocation of a VOR Federal Airway in the Vicinity of Wolbach, NE

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of proposed rulemaking (NPRM).

SUMMARY: This action proposes to amend Jet Routes J–10, J–84, J–100, J–128, J–144, and J–197, VHF Omnidirectional Range (VOR) Federal airways V–172 and V–380, and Area Navigation (RNAV) route T–288; and revoke VOR Federal airway V–219. The FAA is proposing this action due to the planned decommissioning of the VOR portion of the Wolbach, NE (OBH), VOR/Tactical Air Navigation (VORTAC) navigational aid (NAVAID). The Wolbach VOR is being decommissioned in support of the FAA's VOR Minimum Operational Network (MON) program.

DATES: Comments must be received on or before January 6, 2023.

ADDRESSES: Send comments on this proposal to the U.S. Department of Transportation, Docket Operations, 1200 New Jersey Avenue SE, West Building Ground Floor, Room W12–140, Washington, DC 20590; telephone: 1(800) 647–5527, or (202) 366–9826. You must identify FAA Docket No. FAA–2022–1395 Airspace Docket No. 22–ACE–10 at the beginning of your comments. You may also submit comments through the internet at www.regulations.gov.

FAA Order JO 7400.11G, Airspace Designations and Reporting Points, and subsequent amendments can be viewed online at www.faa.gov/air_traffic/publications/. For further information, you can contact the Rules and Regulations Group, Federal Aviation Administration, 800 Independence Avenue SW, Washington, DC 20591; telephone: (202) 267–8783.

FOR FURTHER INFORMATION CONTACT:

Colby Abbott, Rules and Regulations Group, Office of Policy, Federal Aviation Administration, 800 Independence Avenue SW, Washington, DC 20591; telephone: (202) 267-8783.

SUPPLEMENTARY INFORMATION:**Authority for This Rulemaking**

The FAA's authority to issue rules regarding aviation safety is found in Title 49 of the United States Code. Subtitle I, Section 106 describes the authority of the FAA Administrator. Subtitle VII, Aviation Programs, describes in more detail the scope of the agency's authority. This rulemaking is promulgated under the authority described in Subtitle VII, Part A, Subpart I, Section 40103. Under that section, the FAA is charged with prescribing regulations to assign the use of the airspace necessary to ensure the safety of aircraft and the efficient use of airspace. This regulation is within the scope of that authority as it would modify the ATS route structure as necessary to preserve the safe and efficient flow of air traffic within the National Airspace System.

Comments Invited

Interested parties are invited to participate in this proposed rulemaking by submitting such written data, views, or arguments as they may desire. Comments that provide the factual basis supporting the views and suggestions presented are particularly helpful in developing reasoned regulatory decisions on the proposal. Comments are specifically invited on the overall regulatory, aeronautical, economic, environmental, and energy-related aspects of the proposal.

Communications should identify both docket numbers (FAA Docket No. FAA-2022-1395 Airspace Docket No. 22-ACE-10) and be submitted in triplicate to the Docket Management Facility (see **ADDRESSES** section for address and phone number). You may also submit comments through the internet at www.regulations.gov.

Commenters wishing the FAA to acknowledge receipt of their comments on this action must submit with those comments a self-addressed, stamped postcard on which the following statement is made: "Comments to FAA Docket No. FAA-2022-1395 Airspace Docket No. 22-ACE-10." The postcard will be date/time stamped and returned to the commenter.

All communications received on or before the specified comment closing date will be considered before taking action on the proposed rule. The proposal contained in this action may

be changed in light of comments received. All comments submitted will be available for examination in the public docket both before and after the comment closing date. A report summarizing each substantive public contact with FAA personnel concerned with this rulemaking will be filed in the docket.

Availability of NPRMs

An electronic copy of this document may be downloaded through the internet at www.regulations.gov. Recently published rulemaking documents can also be accessed through the FAA's web page at www.faa.gov/air_traffic/publications/airspace_amendments/.

You may review the public docket containing the proposal, any comments received and any final disposition in person in the Dockets Office (see **ADDRESSES** section for address and phone number) between 9:00 a.m. and 5:00 p.m., Monday through Friday, except Federal holidays. An informal docket may also be examined during normal business hours at the office of the Operations Support Group, Central Service Center, Federal Aviation Administration, 10101 Hillwood Parkway, Fort Worth, TX, 76177.

Availability and Summary of Documents for Incorporation by Reference

This document proposes to amend FAA Order JO 7400.11G, Airspace Designations and Reporting Points, dated August 19, 2022, and effective September 15, 2022. FAA Order JO 7400.11G is publicly available as listed in the **ADDRESSES** section of this document. FAA Order JO 7400.11G lists Class A, B, C, D, and E airspace areas, air traffic service routes, and reporting points.

Background

The FAA is planning to decommission the Wolbach, NE, VOR in June 2023. The Wolbach VOR was one of the candidate VORs identified for discontinuance by the FAA's VOR MON program and listed in the Final policy statement notice, "Provision of Navigation Services for the Next Generation Air Transportation System (NextGen) Transition to Performance-Based Navigation (PBN) (Plan for Establishing a VOR Minimum Operational Network)," published in the **Federal Register** of July 26, 2016 (81 FR 48694), Docket No. FAA-2011-1082.

Although the VOR portion of the Wolbach VORTAC is planned for decommissioning, the co-located Distance Measuring Equipment (DME)

portion of the NAVAID is being retained to support NextGen PBN flight procedure requirements.

The Air Traffic Service (ATS) routes effected by the Wolbach VOR decommissioning are Jet Routes J-10, J-84, J-100, J-128, J-144, and J-197; VOR Federal airways V-172, V-219, and V-380; and RNAV route T-288. With the planned decommissioning of the Wolbach VOR, the remaining ground-based NAVAID coverage in the area is insufficient to enable the continuity of the affected ATS routes. As such, proposed modifications to J-10, J-84, J-100, and J-128 would result in a gap being created in the ATS routes; to J-144, J-197, V-172, and V-380 would result in the ATS routes being shortened; to T-288 would result in the Wolbach VOR/DME end point being changed; and to V-219 would result in the airway being revoked.

To overcome the proposed modifications to the affected ATS routes, instrument flight rules (IFR) traffic in the high altitude enroute structure could use portions of Jet Routes J-44, J-60, J-94, J-114, J-146, J-148, and J-151 for conventional navigation or RNAV routes Q-92, Q-114, Q-122, and Q-136 for Global Positioning Satellite (GPS) navigation for properly equipped aircraft. IFR traffic in the low altitude enroute structure could use portions of VOR Federal airways V-6, V-8, V-71, V-80, and V-148 for conventional navigation or RNAV routes T-286, T-288, T-302, and T-413 for GPS navigation for properly equipped aircraft. Additionally, pilots equipped with RNAV capabilities could also navigate point to point using the existing NAVAIDs and fixes that would remain in place to support continued operations through the affected area. Visual flight rules (VFR) pilots who elect to navigate via the affected ATS routes could also take advantage of the adjacent ATS routes or ATC services listed previously. Lastly, IFR and VFR aircraft may request and receive air traffic control (ATC) radar vectors to fly around or through the affected area.

Further, RNAV route T-288 would be amended to change the Wolbach VORTAC route end point to a new route end point located near the Wolbach VORTAC. This T-288 amendment action would be aimed at retaining the safety and efficiency of the route while minimizing impact to the RNAV route's structure.

The Proposal

The FAA is proposing an amendment to 14 CFR part 71 to amend Jet Routes J-10, J-84, J-100, J-128, J-144, and J-

197, VHF Omnidirectional Range (VOR) Federal airways V-172 and V-380, and Area Navigation (RNAV) route T-288; and revoke VOR Federal airway V-219 due to the planned decommissioning of the VOR portion of the Wolbach, NE, VORTAC. The proposed ATS route actions are described below.

J-10: J-10 currently extends between the Los Angeles, CA, VORTAC and the Iowa City, IA, VOR/Distance Measuring Equipment (VOR/DME). The FAA proposes to remove the route segment overlying the Wolbach VORTAC between the North Platte, NE, VOR/DME and the Des Moines, IA, VORTAC. As amended, the route would extend between the Los Angeles VORTAC and the North Platte VOR/DME, and between the Des Moines VORTAC and the Iowa City VOR/DME.

J-84: J-84 currently extends between the Oakland, CA, VOR/DME and the Danville, IL, VORTAC. The FAA proposes to remove the route segment overlying the Wolbach VORTAC between the Sidney, NE, VOR/DME and the Dubuque, IA, VORTAC. As amended, the route would extend between the Oakland VOR/DME and the Sidney VOR/DME, and between the Dubuque VORTAC and the Danville VORTAC.

J-100: J-100 currently extends between the Los Angeles, CA, VORTAC and the Northbrook, IL, VORTAC. The FAA proposes to remove the route segment overlying the Wolbach VORTAC between the Sidney, NE, VOR/DME and the Dubuque, IA, VORTAC. As amended, the route would extend between the Los Angeles VORTAC and the Sidney VOR/DME, and between the Dubuque VORTAC and the Northbrook VORTAC.

J-128: J-128 currently extends between the Los Angeles, CA, VORTAC and the Northbrook, IL, VORTAC. The FAA proposes to remove the route segment overlying the Wolbach VORTAC between the Hayes Center, NE, VORTAC and the Dubuque, IA, VORTAC. As amended, the route would extend between the Los Angeles VORTAC and the Hayes Center VORTAC, and between the Dubuque VORTAC and the Northbrook VORTAC.

J-144: J-144 currently extends between the Wolbach, NE, VORTAC and the Dubuque, IA, VORTAC. The FAA proposes to remove the route segment overlying the Wolbach VORTAC between the Wolbach VORTAC and the Des Moines, IA, VORTAC. As amended, the route would extend between the Des Moines VORTAC and the Dubuque VORTAC.

J-197: J-197 currently extends between the Dove Creek, CO, VORTAC

and the Sioux Falls, SD, VORTAC. The FAA proposes to remove the route segment overlying the Wolbach VORTAC between the Goodland, KS, VORTAC and Sioux Falls, SD, VORTAC. As amended, the route would extend between the Dove Creek VORTAC and the Goodland VORTAC.

V-172: V-172 currently extends between the North Platte, NE, VOR/DME and the DuPage, IL, VOR/DME. The FAA proposes to remove the airway segment overlying the Wolbach VORTAC between the North Platte, NE, VOR/DME and the Columbus, NE, VOR/DME. As amended, the airway would extend between the Columbus VOR/DME and the DuPage VOR/DME.

V-219: V-219 currently extends between the Hayes Center, NE, VORTAC and the Norfolk, NE, VOR/DME. The FAA proposes to remove the airway in its entirety.

V-380: V-380 currently extends between the O'Neill, NE, VORTAC and the Mankato, KS, VORTAC. The airspace within the O'Neill Military Operations Area (MOA) is excluded when the MOA is activated by Notice to Air Missions (NOTAM). The FAA proposes to remove the airway segment overlying the Wolbach VORTAC between the O'Neill, NE, VORTAC and the Grand Island, NE, VOR/DME, and the airway exclusion. As amended, the airway would extend between the Grand Island VOR/DME and the Mankato VORTAC.

T-288: T-288 currently extends between the Gillette, WY, VOR/DME and the Wolbach, NE, VORTAC. The FAA proposes to replace the Wolbach VORTAC route point with the ISTIQ, NE, waypoint (WP) that is located 3 nautical miles northeast of the Wolbach VORTAC on RNAV route T-413. Additionally, the Rapid City, SD, VORTAC latitude/longitude geographic coordinates are updated to match the FAA's National Airspace System Resource database information. As amended, the route would extend between the Gillette VOR/DME and the ISTIQ WP.

All NAVAID radials listed in the ATS route descriptions below are unchanged and stated in True degrees.

Jet Routes are published in paragraph 2004, VOR Federal airways are published in paragraph 6010(a), and United States Area Navigation Routes (T-routes) are published in paragraph 6011 of FAA Order JO 7400.11G, dated August 19, 2022, and effective September 15, 2022, which is incorporated by reference in 14 CFR 71.1. The ATS routes listed in this document would be published subsequently in FAA Order JO 7400.11.

FAA Order JO 7400.11, Airspace Designations and Reporting Points, is published yearly and effective on September 15.

Regulatory Notices and Analyses

The FAA has determined that this proposed regulation only involves an established body of technical regulations for which frequent and routine amendments are necessary to keep them operationally current. It, therefore: (1) is not a "significant regulatory action" under Executive Order 12866; (2) is not a "significant rule" under Department of Transportation (DOT) Regulatory Policies and Procedures (44 FR 11034; February 26, 1979); and (3) does not warrant preparation of a regulatory evaluation as the anticipated impact is so minimal. Since this is a routine matter that will only affect air traffic procedures and air navigation, it is certified that this proposed rule, when promulgated, will not have a significant economic impact on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

Environmental Review

This proposal will be subject to an environmental analysis in accordance with FAA Order 1050.1F, "Environmental Impacts: Policies and Procedures," prior to any FAA final regulatory action.

List of Subjects in 14 CFR Part 71

Airspace, Incorporation by reference, Navigation (air).

The Proposed Amendment

In consideration of the foregoing, the Federal Aviation Administration proposes to amend 14 CFR part 71 as follows:

PART 71—DESIGNATION OF CLASS A, B, C, D, AND E AIRSPACE AREAS; AIR TRAFFIC SERVICE ROUTES; AND REPORTING POINTS

■ 1. The authority citation for 14 CFR part 71 continues to read as follows:

Authority: 49 U.S.C. 106(f), 106(g); 40103, 40113, 40120; E.O. 10854, 24 FR 9565, 3 CFR, 1959–1963 Comp., p. 389.

§ 71.1 [Amended]

■ 2. The incorporation by reference in 14 CFR 71.1 of FAA Order JO 7400.11G, Airspace Designations and Reporting Points, dated August 19, 2022, and effective September 15, 2022, is amended as follows:

Paragraph 2004 Jet Routes.

* * * * *

J-10 [Amended]

From Los Angeles, CA; INT Los Angeles 083° and Twentynine Palms, CA, 269° radials; Twentynine Palms; INT Twentynine Palms 075° and Flagstaff, AZ, 251° radials; Flagstaff; Rattlesnake, NM; Blue Mesa, CO; Falcon, CO; to North Platte, NE. From Des Moines, IA; to Iowa City, IA.

* * * * *

J-84 [Amended]

From Oakland, CA; Linden, CA; Mina, NV; Delta, UT; Meeker, CO; to Sidney, NE. From Dubuque, IA; Northbrook, IL; to Danville, IL.

* * * * *

J-100 [Amended]

From Los Angeles, CA; Daggett, CA; Las Vegas, NV; INT of Las Vegas 046° and Bryce Canyon, UT, 240° radials; Bryce Canyon;

Meeker, CO; to Sidney, NE. From Dubuque, IA; to Northbrook, IL.

* * * * *

J-128 [Amended]

From Los Angeles, CA; INT Los Angeles 083° and Peach Springs, AZ, 244° radials; Peach Springs; Tuba City, AZ; Blue Mesa, CO; Falcon, CO; to Hayes Center, NE. From Dubuque, IA; to Northbrook, IL.

* * * * *

J-144 [Amended]

From Des Moines, IA; to Dubuque, IA.

* * * * *

J-197 [Amended]

From Dove Creek, CO; Hugo, CO; to Goodland, KS.

* * * * *

Paragraph 6010(a) Domestic VOR Federal Airways.

* * * * *

V-172 [Amended]

From Columbus, NE; Omaha, IA; INT Omaha 066° and Newton, IA, 262° radials; Newton; Cedar Rapids, IA; Polo, IL; INT Polo 088° and DuPage, IL, 293° radials; to DuPage.

* * * * *

V-219 [Removed]

* * * * *

V-380 [Amended]

From Grand Island, NE; Hastings, NE; to Mankato, KS.

* * * * *

Paragraph 6011 United States Area Navigation Routes.

* * * * *

T-288 GILLETTE, WY (GCC) TO ISTIQ, NE [AMENDED]

Gillette, WY (GCC)	VOR/DME	(Lat. 44°20'51.98" N, long. 105°32'36.55" W)
KARAS, WY	FIX	(Lat. 44°16'22.88" N, long. 104°18'49.64" W)
Rapid City, SD (RAP)	VORTAC	(Lat. 43°58'33.74" N, long. 103°00'44.38" W)
WNDED, SD	WP	(Lat. 43°19'14.00" N, long. 101°32'19.00" W)
Valentine, NE (VTN)	NDB	(Lat. 42°51'41.85" N, long. 100°32'58.73" W)
Ainsworth, NE (ANW)	VOR/DME	(Lat. 42°34'08.81" N, long. 099°59'22.78" W)
FESNT, NE	WP	(Lat. 42°03'57.00" N, long. 099°17'18.00" W)
ISTIQ, NE	WP	(Lat. 41°24'52.04" N, long. 098°24'18.89" W)

* * * * *

Issued in Washington, DC, on November 16, 2022.

Scott M. Rosenbloom,

Manager, Airspace Rules and Regulations.

[FR Doc. 2022-25418 Filed 11-21-22; 8:45 am]

BILLING CODE 4910-13-P

DEPARTMENT OF COMMERCE**Census Bureau****15 CFR Part 90**

[Docket Number: 221116-0243]

RIN 0607-AA60

Resumption of the Population Estimates Challenge Program and Proposed Changes to the Program

AGENCY: Census Bureau, Department of Commerce.

ACTION: Notice of proposed rulemaking and request for comments.

SUMMARY: The Bureau of the Census (Census Bureau) is proposing to amend the regulations for the Population Estimates Challenge Program which provides eligible general-purpose governmental entities (units) with the opportunity to file requests for the review of their population estimates for 2021 and subsequent years in

forthcoming estimates series, beginning with the Vintage 2022 series that is scheduled to be published in 2023. Under this program, a governmental unit may file a challenge to its official population estimate by submitting additional data to the Census Bureau for evaluation, or by identifying a technical error in processing input data or producing the estimates. Specifically, the Census Bureau is proposing to amend its regulations to: update references to the input data used to produce the official population estimates and revise the evidence required to support a challenge.

DATES: Written comments must be submitted on or before December 22, 2022.

ADDRESSES: Interested persons are invited to submit written comments by email to POP.challenge@census.gov. You also may submit comments, identified by RIN number 0607-AA60, to the Federal e-Rulemaking Portal: <https://www.regulations.gov>. All comments received are a part of the public record. Comments will be posted to <https://www.regulations.gov> for public viewing on a rolling basis. Comments generally will be posted without change. All Personal Identifying Information (for example, name, address) voluntarily submitted by the commenter may be publicly accessible.

Do not submit Confidential Business Information or otherwise sensitive or protected information. The Census Bureau will accept anonymous comments (enter N/A in the required fields, if you wish to remain anonymous). You may submit attachments to electronic comments in Microsoft Word, Excel, or Adobe PDF file formats only.

FOR FURTHER INFORMATION CONTACT:

Requests for additional information should be directed to Amel Toukabri, Chief, Local Government Estimates and Migration Processing Branch, Population Division, 301-763-2461 or POP.challenge@census.gov.

SUPPLEMENTARY INFORMATION:**Background**

The Census Bureau typically releases annual population estimates, in accordance with Title 13 of the United States Code (U.S.C.). These estimates are typically based to some extent upon the most recent Decennial Census of Population and Housing and compiled from the most current administrative and survey data available for that purpose. Although not required by any statute, the Census Bureau also typically offers an opportunity for local units of general-purpose government (hereinafter collectively "governmental unit") to challenge these official estimates through its Population

Estimates Challenge Program. Under this program, a governmental unit may challenge its population estimate by submitting additional data to the Census Bureau for evaluation, or by identifying a technical error in processing input data or producing the estimates. If the additional data are accepted during the review period by the Census Bureau, resulting in an updated population estimate, the Census Bureau will provide a written notification to the governmental unit and publish the revised estimate at www.census.gov. If the additional data are not accepted for a revised estimate, the Census Bureau will notify the governmental unit. In the challenge process, the Census Bureau will only accept a challenge when the evidence provided indicates the use of incorrect data, processes, or calculations in the estimates.

In this proposed rule, the Census Bureau is proposing to amend its regulations to: (1) update references to the input data used to produce the official population estimates, and (2) revise the evidence required to support a challenge.

The Census Bureau is also soliciting comments from the public about any ways in which the program might be improved. In particular, the Census Bureau welcomes comments about (1) the methodology used in preparing the annual Population Estimates, (2) the sources of data that the agency considers (or does not consider) in preparing the annual Population Estimates, and (3) what sorts of factual or methodological arguments the agency considers (or does not consider) in evaluating a potential challenge.

Currently, the Census Bureau begins the process of preparing population estimates by updating population information from the most recent decennial census and other sources with information found in the annual administrative records of Federal and State Agencies. The Federal Agencies provide tax records, Medicare records, and some vital records and group quarters information. The State Agencies from the Federal-State Cooperative for Population Estimates (FSCPE), designated by their respective governors to work in cooperation with the Census Bureau's Population Estimates Program to produce population estimates, also supply vital statistics and information about group quarters like college dorms or prisons.¹ The Census Bureau combines census base data, administrative records, and selected survey data to produce current

population estimates that usually begin with the last decennial census. Additionally, the Census Bureau's general-purpose governmental units' population estimates are provided to the FSCPE agencies in preliminary form for review and comment to resolve data processing issues identified during that period. For the purposes of this program, the District of Columbia is treated as a statistical equivalent of a county and, therefore, eligible to participate.

A major priority for the Census Bureau is balancing the need to use the 2020 Census counts at the lowest level of estimates geography as the starting point in estimates production with the statutory obligation to protect the respondents' confidentiality at every stage of the data lifecycle. Since the 1990 Census, the Bureau has added "noise"—or variations from the actual count—to the collected data to ensure privacy and confidentiality. For 2020 Census data, the Census Bureau applied noise using a newer disclosure avoidance framework based on "differential privacy".² The Census Bureau uses a housing unit method to distribute a county population to places within its legal boundaries. The components in this method include housing units estimates, average household population per housing unit, and an estimate of the population in group quarters. The estimation formula was simplified to increase the accuracy of the estimates following the application of differential privacy as per the Census Bureau's new disclosure avoidance framework: to minimize the impact of differential privacy on the population estimates, the Census Bureau reduced the number of components requiring privacy protection used to generate population estimates. Consequently, the occupancy rate and Persons Per Household (PPH) previously used in this method were replaced with the average household population per housing unit. The household population and the group quarters population used in the calculation of the estimate are the only two components subject to differential privacy protection compared to three components—occupancy rate, PPH, and group quarters population—that would have otherwise required privacy protection. Therefore, the PPH and occupancy rate components are no longer inputs used to produce those population estimates. The distributive housing unit equation used to calculate

the population estimates for governmental units is simplified to accommodate the application of the disclosure avoidance technique prior to releasing the estimates. As a result, the Census Bureau is proposing to amend 15 CFR part 90 to revise: (1) references to the input data used to produce the official population estimates, (2) where to file a challenge and (3) the evidence required to support a challenge. These changes are captured in the proposed updates to §§ 90.2, 90.7, and 90.8.

The Census Bureau proposes no technical changes to its regulations except in the following sections:

Sections 90.2 and 90.7—to ensure that the regulatory text more accurately describes how the Population Estimates Challenge Program has always functioned and is expected to function in the future. This proposed clarification does not reflect any operational changes.

Section 90.8—to update the challengeable components of change.

Regulatory Flexibility Act

The Regulatory Flexibility Act (RFA), as amended by the Small Business Regulatory Enforcement Fairness Act of 1996 (SBREFA), 5 U.S.C. 601 *et seq.*, generally requires an agency to prepare a regulatory flexibility analysis of any rule subject to the notice and comment rulemaking requirements under the Administrative Procedure Act (5 U.S.C. 553) or any other statute, unless the agency certifies that the rule will not have a significant economic impact on a substantial number of small entities. Under section 605(b) of the RFA, however, if the head of an agency certifies that a rule will not have a significant impact on a substantial number of small entities, the statute does not require the agency to prepare a regulatory flexibility analysis. Pursuant to section 605(b), the Chief Counsel for Regulation, Department of Commerce, submitted a memorandum to the Chief Counsel for Advocacy, Small Business Administration, certifying that this proposed rule will not have a significant impact on a substantial number of small entities.

Number of Small Entities

This proposed rule, if implemented, would impact only governmental units, some of which may be considered a small entity under the RFA. The RFA defines "small entity" as a small business, small organization, or small governmental jurisdiction. Specifically, the RFA defines "small governmental jurisdiction" as the government of a city, county, town, school district, or special district with a population of less

¹ <https://www.census.gov/programs-surveys/popest/about/fscpe.html>.

² For more information about the differential privacy technique, visit Understanding Differential Privacy ([census.gov](https://www.census.gov)).

than 50,000. Using this criterion, the Census Bureau estimates that around 37,000 small governmental jurisdictions would be impacted by this rulemaking.

Economic Impact

The Census Bureau does not anticipate any economic impact as a result of this proposed rule. This rulemaking intends to resume the implementation of the Population Estimates Challenge Program in 2023 to provide eligible entities the opportunity to file a challenge to population estimates for 2021 and subsequent years in forthcoming estimates series, beginning with the Vintage 2022 series that is scheduled to be published in 2023. There are no direct costs imposed on governmental entities (units) that wish to initiate a challenge under the Population Estimates Challenge Program.

Executive Orders

This rulemaking has been determined to be not significant for purposes of Executive Order 12866. This proposed rule does not contain policies with federalism implications as that term is defined in Executive Order 13132.

Paperwork Reduction Act

This notice of proposed rulemaking does not contain a collection of information subject to the requirements of the Paperwork Reduction Act (PRA), 44 U.S.C., Chapter 35. Notwithstanding any other provision of the law, no person is required to respond to, nor shall any person be subject to a penalty for failure to comply with, a collection of information subject to the requirements of the PRA, unless that collection of information displays a currently valid Office of Management and Budget (OMB) Control Number.

Robert L. Santos, Director, Census Bureau, approved the publication of this notification in the **Federal Register**.

List of Subjects in 15 CFR Part 90

Administrative practice and procedure, Census data, Population census, Statistics.

For the reasons set forth in the preamble, Census Bureau proposes to amend 15 CFR part 90 as follows:

PART 90—PROCEDURE FOR CHALLENGING POPULATION ESTIMATES

■ 1. The authority citation for part 90 continues to read as follows:

Authority: 13 U.S.C. 4 and 181.

■ 2. Revise § 90.2 to read as follows:

§ 90.2 Policy of the Census Bureau.

It is the policy of the Census Bureau to provide the most accurate population estimates possible given the constraints of resources and available statistical techniques. It is also the policy of the Census Bureau, to the extent feasible, to provide governmental units the opportunity to seek a review of and provide additional data for these estimates and to present evidence relating to the accuracy of the estimates.

■ 3. Revise § 90.7 to read as follows:

§ 90.7 Where to file a challenge.

A request for a population estimate challenge must be prepared in writing by the governmental unit and filed with the Chief, Population Division, Census Bureau by sending the request via email to POP.challenge@census.gov. The governmental unit must designate a contact person who can be reached by telephone or email during normal business hours should questions arise with regard to the submitted materials.

■ 4. Amend § 90.8 by revising paragraphs (a), (c), and (d) to read as follows:

§ 90.8 Evidence required.

(a) The governmental unit shall provide whatever evidence it has relevant to the request at the time of filing. The Census Bureau may request further evidence when necessary. The evidence submitted must be consistent with the criteria, standards, and regular processes the Census Bureau employs to generate the population estimate. The Census Bureau challenge process cannot accept estimates developed from methods different from those used by the Census Bureau. The Census Bureau will only accept a challenge when the evidence provided indicates the use of incorrect data, processes, or calculations in the estimates.

* * * * *

(c) For minor civil divisions and incorporated places, the Census Bureau uses a housing unit method to distribute a county population to places within its legal boundaries. The components in this method include housing units estimates, average household population per housing unit, and an estimate of the population in group quarters. The estimation formula was simplified to increase the accuracy of the estimates following the application of differential privacy as per the Census Bureau's new disclosure avoidance framework. As a result, the persons per household (PPH) and occupancy rate components were replaced with the average household population per housing unit. Consequently, the PPH and occupancy rate are no longer inputs

used to produce those population estimates and are not eligible to be challenged. The Census Bureau will consider a challenge based on data related to changes in an area's housing stock, such as data on demolitions, condemned units, uninhabitable units, building permits, or mobile home placements or other housing inventory-based data deemed comparable by the Census Bureau. The Census Bureau will also consider a challenge based on additional information about the group quarters population in a locality.

(d) The Census Bureau will also provide a guide on its website as a reference for governmental units to use in developing their data as evidence to support a challenge to the population estimate. In addition, a governmental unit may address any additional questions by contacting the Census Bureau at 301-763-2461 or by sending emails to POP.challenge@census.gov.

Dated: November 17, 2022.

Shannon Wink,

*Program Analyst, Policy Coordination Office,
U.S. Census Bureau.*

[FR Doc. 2022-25415 Filed 11-21-22; 8:45 am]

BILLING CODE 3510-07-P

DEPARTMENT OF THE TREASURY

Internal Revenue Service

26 CFR Part 1

[REG-112096-22]

RIN 1545-BQ46

Guidance Related to the Foreign Tax Credit

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Notice of proposed rulemaking.

SUMMARY: This document contains proposed regulations relating to the foreign tax credit, including guidance with respect to the reattribution asset rule for purposes of allocating and apportioning foreign taxes, the cost recovery requirement, and the attribution rule for withholding tax on royalty payments.

DATES: Written or electronic comments and requests for a public hearing must be received by January 23, 2023.

ADDRESSES: Commenters are strongly encouraged to submit public comments electronically. Submit electronic submissions via the Federal eRulemaking Portal at www.regulations.gov (indicate IRS and REG-112096-22) by following the online instructions for submitting

comments. Once submitted to the Federal eRulemaking Portal, comments cannot be edited or withdrawn. The Department of the Treasury (the “Treasury Department”) and the Internal Revenue Service (the “IRS”) will publish for public availability any comment submitted electronically, and on paper, to its public docket. Send hard copy submissions to: CC:PA:LPD:PR (REG–112096–22), Room 5203, Internal Revenue Service, P.O. Box 7604, Ben Franklin Station, Washington, DC 20044. Submissions may be hand delivered Monday through Friday between the hours of 8 a.m. and 4 p.m. to CC:PA:LPD:PR (REG–112096–22), Courier’s Desk, Internal Revenue Service, 1111 Constitution Avenue NW, Washington, DC 20224.

FOR FURTHER INFORMATION CONTACT:

Concerning §§ 1.901–2 and 1.903–1, Teisha Ruggiero, (646) 259–8116; concerning § 1.861–20, Suzanne Walsh, (202) 317–4908; concerning submissions of comments and requests for a public hearing, Regina Johnson, (202) 317–6901 (not toll-free numbers) or by sending an email to publichearings@irs.gov (preferred).

SUPPLEMENTARY INFORMATION:

Background

On December 17, 2019, the Treasury Department and the IRS published proposed regulations (REG–105495–19) addressing changes made by the Tax Cuts and Jobs Act (Pub. L. 115–97, 131 Stat. 2054 (2017)) (the “TCJA”) and other related foreign tax credit rules in the **Federal Register** (84 FR 69124) (the “2019 Foreign Tax Credit (“FTC”) proposed regulations”). Correcting amendments to the 2019 FTC proposed regulations were published in the **Federal Register** on May 15, 2020 (85 FR 29368). The 2019 FTC proposed regulations were finalized as part of TD 9922, published in the **Federal Register** (85 FR 71998) on November 12, 2020 (the “2020 FTC final regulations”). On the same date, the Treasury Department and the IRS published proposed regulations (REG–101657–20) in the **Federal Register** (85 FR 72078) (the “2020 FTC proposed regulations”). The 2020 FTC proposed regulations addressed changes made by the TCJA and other foreign tax credit issues. Correcting amendments to the 2020 FTC final regulations were published in the **Federal Register** on October 1, 2021 (86 FR 54367). A public hearing on the 2020 FTC proposed regulations was held on April 7, 2021. The 2020 FTC proposed regulations were finalized in TD 9959, published in the **Federal Register** (87 FR 276) on January 4, 2022 (the “2022

FTC final regulations”). Correcting amendments to the 2022 FTC final regulations were published in the **Federal Register** on July 27, 2022 (87 FR 45018 and 87 FR 45021).

This document contains proposed regulations (the “proposed regulations”) addressing the following issues: (1) the definition of a reattribution asset for purposes of allocating and apportioning foreign income taxes; (2) the application of the cost recovery requirement; and (3) the application of the source-based attribution requirement to withholding taxes on certain royalty payments.

Explanation of Provisions

I. Allocation and Apportionment of Foreign Income Taxes

A. In General

Section 1.861–20 provides rules for allocating and apportioning foreign income taxes to the statutory and residual groupings, including the categories described in section 904 that apply for purposes of calculating a taxpayer’s foreign tax credit limitation. In general, § 1.861–20 operates by first assigning the foreign gross income on which the foreign income tax is imposed to statutory and residual groupings based upon the character of the item of U.S. gross income that corresponds to the foreign gross income (the “corresponding U.S. item”). § 1.861–20(c) and (d). Foreign income tax expense is allocated to the grouping to which the foreign gross income is assigned, and if foreign gross income is assigned to more than one grouping, deductions computed under foreign law are allocated and apportioned to the groupings and foreign tax expense is apportioned among the groupings based upon foreign taxable income in the groupings. § 1.861–20(e) and (f).

The 2022 FTC final regulations provide rules for allocating and apportioning foreign income tax arising from a disregarded payment. Foreign gross income included by reason of the receipt of a disregarded payment has no corresponding U.S. item because Federal income tax law does not give effect to the payment as a receipt of gross income. Section 1.861–20(d)(3)(v) therefore characterizes the disregarded payment under Federal income tax law for purposes of assigning this foreign gross income to the statutory and residual groupings. These rules treat the portion of a disregarded payment, if any, that causes U.S. gross income of the payor taxable unit to be reattributed under either § 1.904–4(f)(2) (in the case of a taxpayer that is an individual or domestic corporation) or § 1.951A–2(c)(7)(ii)(B) (in the case of a taxpayer

that is a foreign corporation) to the recipient taxable unit as a “reattribution payment.” § 1.861–20(d)(3)(v)(E)(7); *see also* part I.B of this Explanation of Provisions for a description of the reattribution payment rules. The excess of a disregarded payment over the portion that is a reattribution payment is treated either as a contribution from one taxable unit to another taxable unit owned by the first taxable unit, or as a remittance of a taxable unit’s current and accumulated earnings. § 1.861–20(d)(3)(v)(E)(2) and (8). Section 1.861–20(d)(3)(v)(D) provides a special rule for characterizing disregarded payments that are made in exchange for property and are not reattribution payments.

B. Reattribution Payments, Remittances, and the Reattribution of Assets

Section 1.861–20(d)(3)(v)(B) assigns foreign gross income from a disregarded payment that is a reattribution payment to the same statutory and residual grouping as the U.S. gross income that is reattributed to the recipient taxable unit. This assignment occurs before taking into account any reattribution payments made by the recipient taxable unit.

Foreign gross income included by reason of a remittance is assigned to the statutory and residual groupings by reference to the proportion of the tax book value of the assets of the remitting taxable unit in the groupings as assigned for purposes of apportioning interest expense. § 1.861–20(d)(3)(v)(C)(1)(i). In other words, the character of the assets of the remitting taxable unit is a proxy for the character of the current and accumulated earnings out of which the remittance is made. To more accurately reflect the character of the remitting taxable unit’s earnings, the reattribution asset rule in § 1.861–20(d)(3)(v)(C)(1)(ii) requires that a reattribution of income from one taxable unit (payor taxable unit) to another taxable unit (recipient taxable unit) result in a concomitant reattribution of the tax book value of the assets of the payor taxable unit that generated the reattributed income (“reattribution assets”) from the payor taxable unit to the recipient taxable unit.

After further study, the Treasury Department and the IRS have concluded that the reattribution asset rule is not needed for allocating and apportioning foreign tax on a remittance in the case of disregarded property sales, and particularly with respect to disregarded sales of inventory property. For example, consider a domestic corporation that directly owns two taxable units that are disregarded for U.S. Federal income tax purposes: DE1,

which manufactures inventory property, and DE2, which distributes inventory property to unrelated customers. DE1 sells the manufactured inventory to DE2 in exchange for a disregarded payment. The disregarded payment that DE1 receives for the sale of inventory property to DE2 becomes a reattribution payment when DE2 on-sells the inventory property and generates gain in a transaction that is regarded for U.S. tax purposes. Accordingly, gain from the sale of the inventory is reattributed from the distributing taxable unit to the manufacturing taxable unit, and a portion of the distributing taxable unit's assets is reattributed to the manufacturing taxable unit. Although the assets of the manufacturing taxable unit contributed to the production of the income of both taxable units, the tax book value of the manufacturing taxable unit's assets is not reattributed to the distributing taxable unit. As a result, the reattribution asset rule, by reattributing assets only from the distributor taxable unit to the manufacturing taxable unit, does not more accurately balance among the taxable units all of the assets that produced the gain from the inventory sale. The reattribution of assets instead changes the ratios of the assets considered held by the taxable units such that a greater percentage of the distributor taxable unit's assets consist of non-inventory assets (for example, cash), and a greater percentage of the manufacturing taxable unit's assets consist of inventory.

Accordingly, proposed § 1.861–20(d)(3)(v)(E)(6) retains the general definition of reattribution asset but excludes any portion of the tax book value of property transferred in a disregarded sale from being attributed back to the selling taxable unit. Comments are requested on whether similar revisions should be made to the reattribution asset rule in situations other than disregarded property sales. Comments are further requested on other issues related to the allocation and apportionment of foreign income taxes to disregarded payments, which may be considered in future guidance projects.

II. Creditability of Foreign Taxes Under Sections 901 and 903

A. In General

Section 901 allows a credit for foreign income, war profits, and excess profits taxes, and section 903 provides that such taxes include a tax in lieu of a generally-imposed foreign income, war profits, or excess profits tax (collectively, “foreign income taxes”). Before its amendment by the 2022 FTC final regulations, § 1.901–2(a)(1)

provided that a foreign levy was an income tax if and only if (1) it was a tax, and (2) the predominant character of that tax was that of an income tax in the U.S. sense. Under former § 1.901–2(a)(3), the predominant character of a foreign tax was that of an income tax in the U.S. sense if the tax (1) was likely to reach net gain in the normal circumstances in which it applied (the “net gain requirement”), and (2) was not a “soak-up” tax. To satisfy the net gain requirement, a foreign tax needed to meet the realization, gross receipts, and net income requirements. *See* former § 1.901–2(b).

The 2022 FTC final regulations revised the net gain requirement to better align the regulatory tests with principles in the Internal Revenue Code (“Code”) for determining the base of a U.S. income tax, as well as to simplify and clarify the application of these tests. The revisions made by the 2022 FTC final regulations ensure that a foreign tax is a creditable net income tax only if the determination of the foreign tax base conforms in essential respects to the determination of taxable income under the Code. In particular, the 2022 FTC final regulations limit the role of the predominant character analysis generally required under the prior regulations, which often required empirical analysis, in determining whether a foreign tax meets each of the net gain requirements. Under the 2022 FTC final regulations, a foreign tax satisfies the net gain requirement only if the tax satisfies the realization requirement, the gross receipts requirement, the cost recovery requirement (formerly the net income requirement), and the attribution requirement. In addition, the 2022 FTC final regulations provide that the determination of whether a foreign tax satisfies each component of the net gain requirement is generally based on the terms of the foreign tax law governing the computation of the tax base and not based on empirical analysis. § 1.901–2(b)(1). The 2022 FTC final regulations also maintained the long-standing all-or-nothing rule; that is, a foreign tax either is or is not a foreign income tax, in its entirety, for all persons subject to the foreign tax. § 1.901–2(a)(1)(i).

B. Cost Recovery Requirement

1. Application Under 2022 FTC Final Regulations

Consistent with the net income requirement in former § 1.901–2(b)(4), the 2022 FTC final regulations require, under the cost recovery requirement, that the base of a foreign tax permits the recovery of significant costs and

expenses attributable, under reasonable principles, to the gross receipts included in the tax base. § 1.901–2(b)(4)(i)(A). However, to ensure that a foreign tax is a foreign income tax only if the foreign tax allows for the recovery of costs and expenses in a manner that conforms in essential respects to the determination of taxable income under the Code, and to limit the empirical analysis that would otherwise be required, the 2022 FTC final regulations modified the cost recovery requirement in several respects. For example, the 2022 FTC final regulations provide a list of costs and expenses that are always treated as significant (costs and expenses related to capital expenditures, interest, rents, royalties, wages or other payments for services, and research and experimentation). § 1.901–2(b)(4)(i)(C)(1). Whether other costs and expenses are significant continues to be determined under an empirical analysis; that is, based on whether, for all taxpayers in the aggregate to which the foreign tax applies, the item of cost or expense constitutes a significant portion of the taxpayers' total costs and expenses. *Id.*

However, the 2022 FTC final regulations also recognized that, similar to the United States, foreign countries limit the recovery of certain significant costs and expenses. As a result, § 1.901–2(b)(4)(i)(C)(1) provides that foreign tax law is considered to permit the recovery of significant costs and expenses, even if recovery of certain significant costs and expenses is disallowed in whole or in part, if such disallowance is consistent with any principle underlying the disallowances required under the Code (“principles-based exception”).

2. Response to the 2022 FTC Final Regulations

Following the publication of the 2022 FTC final regulations, the Treasury Department and the IRS have received a number of questions regarding the application of the cost recovery requirement as well as requests to modify the requirement. In particular, taxpayers and other stakeholders identified a number of foreign tax laws that impose disallowances or other limitations on the recovery of costs and expenses that are not clearly matched to a principle underlying a similar disallowance under the Code, even though, in the view of these stakeholders, the foreign tax as a whole is consistent with a net income tax in the U.S. sense. Moreover, taxpayers noted that, in some instances, it was difficult to determine the principle underlying the foreign disallowance

because of a lack of information from the foreign country.

The Treasury Department and the IRS agree that, in certain instances, the cost recovery requirement should be satisfied even if the foreign tax law contains a disallowance or other limitation on the recovery of a particular cost or expense that may not reflect a specific principle underlying a particular disallowance in the Code. The income tax provisions of the Code contain a number of disallowances and other limitations on the deductibility of certain costs and expenses. In some instances, the principle or principles behind the limitation is clear, either because the motivation is articulated in legislative history or because it is possible to determine the principle from the terms of the limitation itself. However, the principles underlying other limitations may be less apparent, making it difficult to determine whether a foreign limitation on the deductibility of certain costs and expenses is consistent with any principle underlying the disallowances under the Code.

As explained in the preamble to the 2022 FTC final regulations, section 901 allows credits for foreign taxes that are income taxes in the U.S. sense, and this standard is met if there is substantial conformity in the principles used to calculate the foreign tax base and the U.S. tax base. Complete conformity between the rules for determining the foreign tax base and the U.S. tax base is not required. Accordingly, the proposed regulations provide additional guidance for evaluating disallowances under foreign tax law that may not mirror the expense disallowance rules in the Code, but that nonetheless do not prevent the foreign tax from being a tax imposed on net income.

Proposed § 1.901–2(b)(4)(i) retains the general cost recovery requirement under the 2022 FTC final regulations, but provides that the relevant foreign tax law need only permit recovery of substantially all of each item of significant cost or expense. Consistent with the general approach of the 2022 FTC final regulations, whether a foreign tax permits recovery of substantially all of each item of significant cost or expense is determined based solely on the terms of the foreign tax law. Proposed § 1.901–2(b)(4)(i)(C)(1).

Proposed § 1.901–2(b)(4)(i)(C)(2) provides a safe harbor for purposes of applying this requirement. Under the safe harbor, a disallowance of a stated portion of an item (or multiple items) of significant cost or expense does not prevent a foreign tax from satisfying the cost recovery requirement if the portion

of the item (or items) that is disallowed does not exceed 25 percent. This safe harbor also permits the foreign tax law to cap deductions of a single item of significant cost or expense or multiple items that relate to a single category of per se significant costs and expenses described in proposed § 1.901–2(b)(4)(i)(B)(2) so long as the cap, based solely on the terms of the foreign tax law, is not less than 15 percent of gross receipts, gross income, or a similar measure, or in the case of a cap based on a percentage of taxable income, or a similar measure, the cap is not less than 30 percent. A foreign law limitation that caps deductions of multiple items that relate to different categories of per se significant costs and expenses at a stated percentage (for example, a cap on the deduction of all interest and royalties, combined, at 15 percent of gross receipts), or that caps deductions of multiple items of significant costs or expense that are significant under proposed § 1.901–2(b)(4)(i)(B)(1) at a stated percentage, would not meet the safe harbor. The safe harbor is intended to provide additional certainty where a foreign tax law disallowance is in the form of a stated portion or cap. Taxpayers will not need to identify a corresponding principle underlying the disallowances required under the Code for foreign tax law disallowances that meet the safe harbor. If the foreign tax law contains a disallowance that is not within the safe harbor, and that otherwise prevents the recovery of substantially all of an item of significant cost or expense, then the limitation would be examined under the principles-based exception from the 2022 FTC final regulations, retained in proposed § 1.901–2(b)(4)(i)(F)(1), which permits more substantial disallowances (including complete disallowances) of an item of significant cost or expense that are consistent with any principle underlying the disallowances required under the Code. The proposed regulations make additional clarifications to this rule, to provide that the principle must be reflected in a disallowance within the income tax provisions of the Code, and if the disallowance addresses a non-tax public policy concern, then such concern must be similar to the non-tax public policy concerns reflected in the Code. In addition, the proposed regulations remove the example of a limit on recovery of interest based upon a measure of taxable income from this principles-based exception because such a limitation would generally be covered by the safe harbor. See proposed § 1.901–2(b)(4)(iv)(H)

(*Example 8*). If the foreign law disallowance does not meet the safe harbor or otherwise permit recovery of substantially all of each item of significant cost or expense, the principles-based exception would be relevant for determining whether the foreign tax could satisfy the cost recovery requirement.

Additionally, proposed § 1.901–2(b)(4)(iv)(F) through (J) provide new examples illustrating the application of the cost recovery requirement. The proposed regulations also reorganize the provisions of the cost recovery requirement to accommodate the addition of these new provisions, as well as to better reflect the structure of the requirement.

C. Attribution Requirement for Royalty Payments

1. Application Under 2022 FTC Final Regulations

The 2022 FTC final regulations added an attribution requirement in § 1.901–2(b)(5) as an element of the net gain requirement to require that a foreign tax conform to the concepts of taxing jurisdiction reflected in the Code that define an income tax in the U.S. sense. The purpose of the attribution requirement is to allow a credit for a foreign tax only if the country imposing the tax has sufficient nexus to the taxpayer's activities or investment of capital that generates the income included in the tax base. This result is consistent with the statutory purpose of the foreign tax credit to relieve double taxation of income through the United States ceding its own taxing rights only where the foreign country has the primary right to tax the income.

With respect to a foreign levy imposed on nonresident taxpayers, the attribution requirement limits the scope of gross receipts and costs included in the base of a foreign tax to those that satisfy the activities-based attribution, source-based attribution, or property-based attribution tests. § 1.901–2(b)(5)(i). These tests are consistent with U.S. income tax principles reflected in the Code's provisions that only tax foreign persons' income that is effectively connected with a U.S. trade or business or attributable to U.S. real property, or that is fixed or determinable annual or periodical (FDAP) income sourced in the United States.

Under the source-based attribution requirement in § 1.901–2(b)(5)(i)(B), a foreign tax imposed on the nonresident's income on the basis of source meets the attribution requirement only if the foreign tax law's

sourcing rules are reasonably similar to the sourcing rules that apply for Federal income tax purposes. In the case of gross income arising from royalties, § 1.901–2(b)(5)(i)(B)(2) provides that the foreign tax law must source royalties based on the place of use of, or the right to use, the intangible property, consistent with how the Code sources royalty income.

For foreign taxes imposed in lieu of an income tax, the 2022 FTC final regulations also modified the substitution requirement in § 1.903–1, including by adding an attribution requirement. Under § 1.903–1(c)(2)(iii), a foreign withholding tax must meet the source-based attribution requirement in § 1.901–2(b)(5)(i)(B) to qualify as a “covered withholding tax” that may be creditable as a tax in lieu of an income tax. Thus, a withholding tax on a royalty payment is creditable only if the foreign tax law sources royalties based upon the place of use of, or the right to use, the intangible property, consistent with how the Code sources royalty income. The 2022 FTC final regulations also maintained the all-or-nothing rule for the substitution requirement; that is, a foreign tax either is or is not a tax in lieu of an income tax, in its entirety, for all persons subject to the foreign tax. § 1.903–1(b)(1). Accordingly, a withholding tax on royalties that is imposed on the basis of the residence of the payor of the royalty is not creditable, whether or not the relevant intangible property is in fact used within the territory of the taxing jurisdiction. § 1.903–1(d)(3) and (4) (*Examples 3 and 4*).

The determination of whether a foreign levy meets the requirements under §§ 1.901–2 and 1.903–1 is made on a levy-by-levy basis. Section 1.901–2(d) provides rules for determining whether one foreign levy is separate from another foreign levy. In general, § 1.901–2(d)(1)(ii) provides that separate levies are imposed on particular classes of taxpayers if the tax base is different for those taxpayers. The 2022 FTC final regulations added a special rule for withholding taxes imposed on nonresidents that treats each such tax as a separate levy with respect to each class of gross income (as listed in section 61) to which the tax applies. § 1.901–2(d)(1)(iii). This rule allows withholding taxes that are imposed on classes of income that are subject to different sourcing rules of the taxing jurisdiction to be analyzed as separate levies under the covered withholding tax requirement in § 1.903–1(c)(2). The 2022 FTC final regulations also provided that if a foreign country imposes a withholding tax on two or

more subsets of a separate class of income and a different source rule applies to each subset of income, then separate levies are considered imposed on each subset of that separate class of income. § 1.901–2(d)(1)(iii). These special rules reflect the general principle in § 1.901–2(d)(1) that the separate levy determination is based upon U.S. principles and not whether foreign tax law imposes the levy or levies pursuant to a single or separate statutes. The rules also enable testing the creditability of a withholding tax on a more granular basis. This approach better reflects the purpose of the attribution requirement to allow a foreign tax credit only where, in the U.S. view, the taxing jurisdiction has the primary right to tax the income.

2. Response to the 2022 FTC Final Regulations

Following the publication of the 2022 FTC final regulations, the Treasury Department and the IRS received questions regarding the application of the source-based attribution requirement to certain royalty withholding taxes. In addition, the Treasury Department and the IRS received requests (including a petition for rulemaking) to change the requirement, by allowing a credit even if a foreign country sources royalties based on the residence of the payor or by applying a different standard.¹

As an initial matter, some taxpayers questioned whether the sourcing rule for royalties was applied differently than that for services because § 1.901–2(b)(5)(i)(B)(1) includes a reference to the use of “reasonable principles” for purposes of applying the source-based attribution requirement to a payment for services, while the equivalent rule in § 1.901–2(b)(5)(i)(B)(2) for royalties does not. Since the introductory text in § 1.901–2(b)(5)(i)(B) states that, in all instances, sourcing rules must be reasonably similar to the sourcing rules under the Code, the same standard applies regardless of whether the relevant payment is for services or for

royalties. However, to avoid further confusion, the proposed regulations conform the language of § 1.901–2(b)(5)(i)(B)(1) and (2).

Additionally, the Treasury Department and the IRS are aware that, in some cases, a taxpayer may license intangible property for use solely within the foreign country in which the licensee is resident, but the foreign country sources royalties based on the residence of the payor. In these cases, notwithstanding the actual use of the licensed property in the taxing jurisdiction, a credit would not be allowed for the royalty withholding tax under the source-based attribution requirement for royalties in § 1.901–2(b)(5)(i)(B). However, in these cases, the foreign country imposing tax on the royalty income should, from a U.S. perspective, have the primary taxing right over the royalty income because the intangible property giving rise to the royalty is in fact being used solely in that foreign country. That is, notwithstanding the difference in sourcing rules for royalty income, there is complete overlap between the jurisdiction with the primary right to tax based on U.S. tax principles and the taxing rights exercised by the taxing jurisdiction.

The Treasury Department and the IRS have concluded that it is appropriate to provide a limited exception to the source-based attribution requirement of the 2022 FTC final regulations where the taxpayer can substantiate that a withholding tax is imposed on royalties received in exchange for the right to use intangible property solely within the territory of the taxing jurisdiction. The Treasury Department and the IRS have concluded that it would be unduly burdensome for both the taxpayer and the IRS to determine the place of use of all intangible property on a country-by-country basis based on each taxpayer’s facts and circumstances. While taxpayers may need to determine the place of use of certain intangible property to determine whether the royalty income is U.S. or foreign source, or for other purposes, those determinations generally do not require taxpayers or the IRS to separately determine the use in a specific foreign country. For this reason, this limited exception applies only if the taxpayer has a written license agreement that provides for the payment of the royalty and that limits the use of the intangible property giving rise to the royalty payment to the territory of the foreign country imposing the tax.

¹ The Treasury Department and the IRS received a petition for rulemaking with respect to the attribution requirement as applied to a tax on a resident but declined to engage in rulemaking on that subject. The Treasury Department and the IRS have determined that the attribution requirement as contained in the 2022 FTC final regulations, including as applied to residents, is appropriate to ensure that a foreign tax is consistent with the general principles of income taxation reflected in the Code. These principles include not only those related to determining realization, gross receipts, and cost recovery, but also principles for determining the scope of the items of gross receipts and costs that may be properly taken into account in computing the tax base on which the foreign tax is imposed.

3. The Single-Country Exception

Reflecting this new limited exception, proposed § 1.903–1(c)(2)(iii) provides that a tested foreign tax satisfies the source-based attribution requirement if the tax meets either the source-based attribution requirement in § 1.901–2(b)(5)(i)(B) or the exception in proposed § 1.903–1(c)(2)(iii)(B) (the “single-country exception”).

In general, the single-country exception applies where (1) the income subject to the tested foreign tax is characterized as gross royalty income, and (2) the payment giving rise to such income is made pursuant to a single-country license. Proposed § 1.903–1(c)(2)(iii)(B). Consistent with § 1.901–2(b)(5)(i)(B), proposed § 1.903–1(c)(2)(iii)(B) provides that foreign tax law generally applies for purposes of determining whether the gross income or gross receipts arising from a transaction are characterized as a royalty, except in the case of a transaction that is considered the sale of a copyrighted article under § 1.861–18, which is not treated as a license of intangible property but as a sale of tangible property.

A payment is made pursuant to a single-country license if the terms of the written license agreement under which the payment is made characterize the payment as a royalty and limit the territory of the license to the foreign country imposing the tested foreign tax. Proposed § 1.903–1(c)(2)(iv)(A). However, a payment (or portion of a payment) may be treated as made pursuant to a single-country license even if the written agreement does not limit the territory of the license to the foreign country imposing the tax or provides for payments in addition to those for the use of intangible property (for example, for related services), if the agreement separately states the portion (whether as a specified amount or as a formula) of the payment subject to the tested foreign tax that is characterized as a royalty and that is with respect to the part of the territory of the license that is solely within the foreign country imposing the tax. *See* proposed §§ 1.903–1(c)(2)(iv)(B) and (d)(9) (*Example 9*).

The Treasury Department and the IRS are aware that, to qualify for the single-country exception, taxpayers may need to revise existing license agreements. Additionally, because certain withholding taxes may remain non-creditable, taxpayers may be incentivized to maximize the portion of a payment that is made pursuant to a single-country license. For example, a taxpayer that receives royalty payments

pursuant to a related-party license agreement that grants the licensee rights to several different types of intangible property—some of which will be exploited solely within the taxing jurisdiction and some outside of the taxing jurisdiction—may be incentivized to amend the related-party license agreement to separately state a royalty amount that purports to qualify for the single-country exception but that may exceed an amount that, under the arm’s length principles of section 482 and sourcing principles of section 861, is attributable to the exploitation of the intangible property within the taxing jurisdiction. Additionally, taxpayers may be disincentivized from revising existing agreements to reflect changes in facts and circumstances if doing so would decrease the amount of the royalty that is eligible for the single-country exception.

To address these concerns, proposed § 1.903–1(c)(2)(iv)(C) provides that a payment is treated as not made pursuant to a single-country license if the taxpayer knows, or has reason to know, that the required agreement misstates the territory in which the intangible property is used or overstates the amount of the royalty with respect to the part of the territory of the license that is solely within the foreign country imposing the tax. Thus, the required agreement must reflect the relevant facts and circumstances, as known by the taxpayer or as would be known by a reasonably prudent person in the position of the taxpayer, regarding both the amount of the relevant royalty and the territory in which the intellectual property is actually used.

In general, a taxpayer cannot qualify for the single-country exception without satisfying the documentation requirement in proposed § 1.903–1(c)(2)(iv)(D). Under proposed § 1.903–1(c)(2)(iv)(D), the required agreement pursuant to which the qualifying royalty is paid must be executed no later than the date on which the royalty is paid. However, recognizing that the single-country exception is proposed to be applicable to periods preceding the release of this notice of proposed rulemaking, a special transition documentation rule is provided for royalties paid on or before May 17, 2023. In that case, to satisfy the documentation requirement, the required agreement must be executed no later than May 17, 2023, and the agreement must state (whether in the terms of the agreement or in recitals) that royalties paid on or before the execution of the agreement are considered paid pursuant to the terms of the agreement.

The required agreement must be maintained by the taxpayer and provided to the IRS within 30 days of a request by the Commissioner or another period as agreed between the Commissioner and the taxpayer. *Id.* For purposes of the rule, the term taxpayer includes a partnership upon which foreign law imposes a tax. *See* § 1.901–2(f)(4) and (g)(7). Therefore, if the royalty withholding tax is imposed at the partnership level, the documentation required by the proposed regulations must be maintained by the partnership, even though the party that claims the credit is the partner and not the partnership. The Treasury Department and the IRS request comments as to whether special rules may be necessary to address the documentation requirement in the case of partnerships.

Finally, proposed § 1.903–1(d)(3) and (8) through (11) provide new examples illustrating the application of the source-based attribution rule and single-country exception for covered withholding taxes on royalties.

4. Separate Levy

The proposed regulations also modify the separate levy rule in § 1.901–2(d)(1)(iii) for withholding taxes imposed on nonresidents. Specifically, § 1.901–2(d)(1)(iii)(B)(3) provides that a withholding tax that is imposed on a royalty payment made to a nonresident pursuant to a single-country license is treated as a separate levy from a withholding tax that is imposed on other royalty payments made to such nonresident and from any other withholding taxes imposed on other nonresidents. As with the special separate levy rule for withholding taxes on different classes of income or different subsets of income within a class of income, this rule may result in a foreign withholding tax being considered a separate levy in cases where the foreign tax law considers only a single levy to be imposed. In contrast to a net income tax, this separate levy rule can be applied to withholding taxes because withholding taxes on royalties are imposed on gross income and on a payment-by-payment basis. In addition, as with the other special levy rules, this separate levy rule better aligns the outcomes of the test with the purposes of the foreign tax credit rules, including that of the attribution requirement. The proposed regulations also reorder and reorganize the paragraphs of proposed § 1.901–2(d)(1)(iii) to accommodate the addition of this new provision, and to reflect the structure of the rules more logically.

III. Applicability Dates

In general, except for proposed § 1.861–20(d)(3)(v)(E)(6), the proposed regulations are proposed to apply to taxable years ending on or after November 18, 2022. However, once the proposed regulations are finalized, taxpayers may choose to apply some or all of the final regulations to earlier taxable years, subject to certain conditions.

Proposed § 1.861–20(d)(3)(v)(E)(6) is proposed to apply to taxable years ending on or after the date final regulations adopting these rules are filed with the **Federal Register**. Taxpayers may choose to apply the rules of § 1.861–20(d)(3)(v)(E)(6), once finalized, to taxable years that begin after December 31, 2019, and end before the date final regulations adopting these rules are filed with the **Federal Register** provided they apply § 1.861–20(d)(3)(v)(E)(6) consistently to their first taxable year beginning after December 31, 2019, and any subsequent taxable year ending before the date final regulations adopting these rules are filed with the **Federal Register**.

Proposed § 1.901–2(b)(4)(i) and (iv), (b)(5)(i)(B)(2), and (d)(1)(iii) and proposed § 1.903–1(c)(2) and (d)(3), (4), and (8) through (11) are proposed to apply to foreign taxes paid in taxable years ending on or after November 18, 2022. Taxpayers may choose to apply the rules of § 1.901–2(b)(4)(i) and (iv), once finalized, for foreign taxes paid in taxable years beginning on or after December 28, 2021, and ending before November 18, 2022, provided that they consistently apply those rules to such taxable years. Taxpayers may also choose to apply the rules of §§ 1.901–2(b)(5)(i)(B)(2) and (d)(1)(iii) and 1.903–1(c)(2) and (d)(3), (4), and (8) through (11), once finalized, for foreign taxes paid in taxable years beginning on or after December 28, 2021, and ending before November 18, 2022, provided that they consistently apply those rules for such taxable years.

Finally, until the effective date of final regulations, a taxpayer may rely on all or part of the proposed regulations, subject to certain conditions. Specifically, a taxpayer may choose to rely on the provisions addressing the reattribution asset rule (proposed § 1.861–20(d)(3)(v)(E)(6)) for taxable years that begin after December 31, 2019, and end before the effective date of final regulations adopting these rules.

A taxpayer may also choose to rely on the provisions addressing the cost recovery requirement (proposed § 1.901–2(b)(4)(i) and (iv)) for foreign taxes paid in taxable years beginning on or after December 28, 2021, and ending before the effective date of final regulations adopting these rules. Finally, a taxpayer may choose to rely on the provisions addressing the attribution requirement for royalty payments (proposed § 1.901–2(b)(5)(i)(B)(2) and (d)(1)(iii) and proposed § 1.903–1(c)(2) and (d)(3), (4), and (8) through (11)) for foreign taxes paid in taxable years beginning on or after December 28, 2021, and ending before the effective date of final regulations adopting these rules.

If a taxpayer chooses to rely on any of the three portions of the proposed regulations described in the preceding paragraph, the taxpayer and its related parties, within the meaning of sections 267(b) (determined without regard to section 267(c)(3)) and 707(b)(1), must consistently follow all proposed regulations with respect to that portion for all relevant years until the effective date of the final regulations adopting the rules.

Conforming Amendments to Other Regulations and Guidance

The Treasury Department and the IRS intend to make conforming amendments to other regulations, including the cost recovery rules that are not being revised in these proposed regulations and the examples in §§ 1.901–2(b)(4)(iv) and 1.903–1(d), upon finalization of the proposed regulations.

Special Analyses

I. Regulatory Planning and Review

The Administrator of the Office of Information and Regulatory Affairs (“OIRA”), Office of Management and Budget, has determined that this proposed rule is not a significant regulatory action, as that term is defined in section 3(f) of Executive Order 12866. Therefore, OIRA has not reviewed this proposed rule pursuant to section 6(a)(3)(A) of Executive Order 12866 and the April 11, 2018, Memorandum of Agreement between the Treasury Department and the Office of Management and Budget (“OMB”).

II. Paperwork Reduction Act

The Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520) (“PRA”) requires that a federal agency obtain the approval

of the OMB before collecting information from the public, whether such collection of information is mandatory, voluntary, or required to obtain or retain a benefit.

A. Overview

The collection of information in these proposed regulations is in proposed § 1.903–1(c)(2)(iv)(D). As discussed in part II.C.3 of the Explanation of Provisions, proposed § 1.903–1(c)(2)(iii)(B) provides an exception (the “single-country exception”) to the source-based attribution requirement if a taxpayer can substantiate that the payment on which the royalty withholding tax is imposed was made pursuant to an agreement that limits the right to use intangible property to the jurisdiction imposing the tested foreign tax. Proposed § 1.903–1(c)(2)(iv)(A). The exception applies only where the taxpayer has a written license agreement that provides for the payment of the royalty and that limits the use of the intangible property giving rise to the royalty payment to the territory of the foreign country imposing the tax. A payment may also qualify for the single-country exception if the agreement separately states the portion (whether as a specified amount or as a formula) of the payment subject to the tested foreign tax that is characterized as a royalty and that is with respect to the portion of the territory of the license that is solely within the foreign country imposing the tax. Proposed § 1.903–1(c)(2)(iv)(B).

Proposed § 1.903–1(c)(2)(iv)(D) requires taxpayers who claim eligibility for the exception to provide an agreement described in proposed § 1.903–1(c)(2)(iv)(A) or (B), as applicable, (the “required agreement”) within 30 days of a request by the Commissioner or another period as agreed between the Commissioner and the taxpayer. Proposed § 1.903–1(c)(2)(iv)(D) also provides a transition rule in the case of a royalty paid on or before May 17, 2023, that requires the required agreement to be executed no later than May 17, 2023.

B. Collection of Information—Proposed § 1.903–1(c)(2)(iv)(D)

The Treasury Department and the IRS intend that the information collection requirement in proposed § 1.903–1(c)(2)(iv)(D) will be set forth in the forms and instructions identified in Table 1.

TABLE 1—TAX FORMS IMPACTED

Collection of information	Number of respondents (estimated)	Forms to which the information may be attached
Proposed § 1.903–1(c)(2)(iv)(D)	≈ 42,030	Form 1116 and Form 1118.

Source: IRS's Compliance Data Warehouse.

The estimate for the number of impacted filers with respect to the collection of information in proposed § 1.903–1(c)(2)(iv)(D) is based on the number of U.S. corporations that filed a return that had a Form 1118 that reported an amount of withholding tax on rents, royalties, and license fees on Schedule B, Part I, column e; U.S. corporations that filed a return that had a Form 1118 that reported an amount of deemed paid taxes and a Form 5471 that reported an amount of gross royalties and license fees on Schedule C (and thus may have incurred a withholding tax on those royalties); and U.S. individuals that filed a return and had a Form 1116 that reported an amount of withholding tax on rents and royalties on Part II, column n.³ This represents an upper bound of potentially affected taxpayers: not all taxpayers that have reported an amount of royalty withholding tax paid to a foreign country or that have royalty income on which they may have paid a withholding tax are expected to claim a

credit for such tax, and not all taxpayers who claim such a credit are expected to rely on the single country exception in proposed § 1.903–1(c)(2)(iii)(B).

The Treasury Department and the IRS expect that taxpayers subject to the collection of information in proposed § 1.903–1(c)(2)(iv)(D) will not have a significant increase in burden (if any) because some taxpayers may already have existing license agreements that qualify for the single-country exception in place for a variety of tax and non-tax law reasons, and other taxpayers may not elect to take advantage of the single-country exception. The reporting burden associated with this collection of information will be reflected in future PRA submissions associated with Form 1118 (OMB control number 1545–0123), Form 1065 (OMB control number 1545–0123), and Form 1116 (OMB control numbers 1545–0074 for individuals, and 1545–0121 for estates and trusts). The collection of information in proposed § 1.903–1(c)(2)(iv)(D) will be reflected in future Paperwork Reduction Act

submissions that the Treasury Department and the IRS will submit to OMB for these forms. The current status of the Paperwork Reduction Act submissions related to these forms is summarized in Table 2.

Because the proposed regulations, including the collection of information in proposed § 1.903–1(c)(2)(iv)(D), are proposed to apply to taxes paid in taxable years ending on or after the date the proposed regulations are filed with the **Federal Register**, the Treasury Department and the IRS have submitted the collection of information in proposed § 1.903–1(c)(2)(iv)(D) to the OMB for review in accordance with the Paperwork Reduction Act and requested a new OMB control number (the “temporary OMB control number”). After the rulemaking is finalized, the information collection contained within the regulations will be incorporated into the OMB control numbers described in Table 2.

TABLE 2—STATUS OF CURRENT PAPERWORK REDUCTION SUBMISSIONS

Form	Type of filer	Temporary OMB control No.	Incorporated into OMB control No.(s) after final rulemaking
Form 1116	Trusts & estates	1545–NEW	1545–0121
	Individual	1545–NEW	1545–0074
Form 1118	Business	1545–NEW	1545–0123

Commenters are strongly encouraged to submit public comments electronically. Comments and recommendations for the proposed information collection should be sent to <https://www.reginfo.gov/public/do/PRAMain>, with electronic copies emailed to the IRS at pra.comments@irs.gov (indicate REG–112096–22 on the subject line). This particular information collection can be found by selecting “Currently under Review—Open for Public Comments” then by

using the search function. Comments can also be mailed to OMB, Attn: Desk Officer for the Department of the Treasury, Office of Information and Regulatory Affairs, Washington, DC 20503, with copies mailed to the IRS, Attn: IRS Reports Clearance Officer, SE:W:CAR:MP:T:T:SP, Washington, DC 20224. Comments on the collections of information should be received by January 23, 2023.

The likely respondents associated with the temporary OMB control

number are U.S. persons who pay or accrue foreign withholding taxes on royalty income.

Estimated total annual reporting burden: 420,300 hours.

Estimated average annual burden per respondent: 10 hours.

Estimated number of respondents: 42,030.

Estimated frequency of responses: Annually.

The Treasury Department and the IRS expect to add the burden for this

² The estimated number of respondents in this Table 1 is based on the number of respondents from the 2020 tax year.

³ As explained in part II.C.3 of the Explanation of Provisions, the collection of information in proposed § 1.903–1(c)(2)(iv)(D) also impacts partnerships and S corporations that pay a

withholding tax that is imposed at the partnership or S corporation level under foreign law even though it is the partners or S corporation shareholder that claims the credit for those taxes. The Treasury Department and the IRS lack sufficient data to identify the number of partnerships and S corporations that pay foreign

withholding taxes on royalty income. However, the IRS and Treasury Department do not expect that this will impact the number of affected taxpayers since the partners and shareholders that claim a credit for the royalty withholding tax would be captured within the Form 1116 and Form 1118 filers.

temporary OMB control number to OMB control numbers 1545–0123, 1545–0074, and 1545–0121 after the final rulemaking. For 1545–0123 and 1545–0074, the Treasury Department and the IRS estimate burdens on a taxpayer-type basis rather than a provision-specific basis.

III. Regulatory Flexibility Act

Pursuant to the Regulatory Flexibility Act (5 U.S.C. chapter 6), it is hereby certified that the proposed regulations will not have a significant economic impact on a substantial number of small entities within the meaning of section 601(6) of the Regulatory Flexibility Act.

The proposed regulations provide guidance affecting individuals and corporations claiming foreign tax credits. The domestic small business entities that are subject to the foreign tax credit rules in the Code and in the proposed regulations are generally those that operate in a foreign country or that have income from sources outside of the

United States and pay foreign taxes. The reattribution asset definition in proposed § 1.861–20(d)(3)(v)(E)(6) applies only to taxable units that make or receive disregarded payments that are considered reattribution payments which result in the reattribution of assets from one taxable unit to another. § 1.861–20(d)(3)(v)(C)(1)(ii). In addition, some provisions of these proposed regulations, such as proposed § 1.903–1, apply only to entities that license intellectual property for use in a foreign country and receive royalty payments that are subject to foreign withholding tax. The Treasury Department and the IRS do not expect that the proposed regulations will likely affect a substantial number of domestic small business entities because it is infrequent for domestic small entities to engage in significant foreign operations or in the types of transactions giving rise to the foreign taxes addressed by these proposed regulations. However, the Treasury Department and the IRS do not

have adequate data readily available to assess the number of small entities potentially affected by the final regulations.

The Treasury Department and the IRS have determined that the proposed regulations will not have a significant economic impact on domestic small business entities. To provide an upper bound estimate of the impact these final regulations could have on business entities, the Treasury Department and the IRS calculated, based on e-file data for the 2020 tax year, foreign tax credits as a percentage of four different tax-related measures of annual receipts (see Table 3 for variables) by corporations. As demonstrated by the data in Table 3 below, foreign tax credits as a percentage of all four measures of annual receipts are substantially less than the three to five percent threshold for significant economic impact for corporations with business receipts less than \$250 million.

TABLE 3—FTCS AS PERCENTAGE OF ANNUAL RECEIPTS

Size (by business receipts)	Under \$500k	\$500k to \$1M	\$1M to \$5M	\$5M to \$10M	\$10M to \$50M	\$50M to \$100M	\$100M to \$250M	\$250M or more
FTC/Gross Receipts (%)	0.00	0.00	0.00	0.01	0.01	0.02	0.03	0.05
FTC/Business Receipts (%)	0.00	0.00	0.00	0.00	0.01	0.02	0.03	0.05
FTC/Total Income (%)	0.00	0.00	0.00	0.01	0.02	0.04	0.07	0.07
FTC/(Total Income—Total Deductions) (%)	–0.02	0.03	0.05	0.11	0.16	0.41	0.72	3.33

Source: RAAS:KDA (Tax Year 2020 CDW E-File Data 9–26–22).

Note: Business Receipts = Total Income + Cost of Goods Sold.

The Treasury Department and the IRS anticipate that only a small fraction of existing foreign tax credits would be impacted by these regulations, and thus, the economic impact of these regulations will be considerably smaller than the effects shown in Table 3. A portion of economic impact of these proposed regulations derive from the collection of information requirement in proposed § 1.903–1(c)(2)(iv)(D). The Treasury Department and the IRS do not have readily available data to determine the incremental burden that this collection of information will have on small business entities. However, the Treasury Department and the IRS believe this collection of information will only marginally increase taxpayers' burdens because some taxpayers may already have existing license agreements that qualify for the single-country exception for a variety of tax and non-tax law reasons, and other taxpayers may not elect to take advantage of the single-country exception. Furthermore, as demonstrated in Table 3 in this Part III of the Special Analyses, foreign tax credits do not have a significant

economic impact for any gross-receipts class of business entities. Therefore, proposed § 1.903–1(c)(2)(iv)(D) will not have a significant economic impact on small business entities. Accordingly, it is hereby certified that the proposed regulations will not have a significant economic impact on a substantial number of small entities.

IV. Section 7805(f)

Pursuant to section 7805(f), these proposed regulations will be submitted to the Chief Counsel for Advocacy of the Small Business Administration for comment on its impact on small businesses. The Treasury Department and the IRS also request comments from the public on the certifications in this Part III of the Special Analyses.

V. Unfunded Mandates Reform Act

Section 202 of the Unfunded Mandates Reform Act of 1995 (UMRA) requires that agencies assess anticipated costs and benefits and take certain other actions before issuing a final rule that includes any Federal mandate that may result in expenditures in any one year by a state, local, or tribal government, in

the aggregate, or by the private sector, of \$100 million in 1995 dollars, updated annually for inflation. This proposed rule does not include any Federal mandate that may result in expenditures by state, local, or tribal governments, or by the private sector in excess of that threshold.

VI. Executive Order 13132: Federalism

Executive Order 13132 (entitled “Federalism”) prohibits an agency from publishing any rule that has federalism implications if the rule either imposes substantial, direct compliance costs on State and local governments, and is not required by statute, or preempts State law, unless the agency meets the consultation and funding requirements of section 6 of the Executive order. This proposed rule does not have federalism implications and does not impose substantial direct compliance costs on state and local governments or preempt State law within the meaning of the Executive order.

Comments and Request for Public Hearing

Before these proposed regulations are adopted as final regulations, consideration will be given to any comments that are submitted timely to the IRS as prescribed in this preamble under the **ADDRESSES** heading. The Treasury Department and the IRS request comments on all aspects of the proposed rules, and specifically on the issues identified in Parts I.B and II.C.3 of the Explanation of Provisions. All comments will be available at www.regulations.gov or upon request.

A public hearing will be scheduled if requested in writing by any person that timely submits written comments. Requests for a public hearing are encouraged to be made electronically. If a public hearing is scheduled, notice of the date and time for the public hearing will be published in the **Federal Register**. Announcement 2020–4, 2020–17 IRB 1, provides that until further notice, public hearings conducted by the IRS will be held telephonically. Any telephonic hearing will be made accessible to people with disabilities.

Drafting Information

The principal authors of the proposed regulations are Jeffrey L. Parry, Teisha M. Ruggiero, and Suzanne M. Walsh of the Office of Associate Chief Counsel (International). However, other personnel from the Treasury Department and the IRS participated in their development.

List of Subjects in 26 CFR Part 1

Income taxes, Reporting and recordkeeping requirements.

Proposed Amendments to the Regulations

Accordingly, the Treasury Department and IRS propose to amend 26 CFR part 1 as follows:

PART 1—INCOME TAXES

■ **Paragraph 1.** The authority citation for part 1 continues to read in part as follows:

Authority: 26 U.S.C. 7805 * * *

■ **Par. 2.** Section 1.861–20 is amended by revising paragraphs (d)(3)(v)(E)(6) and (i) to read as follows:

§ 1.861–20 Allocation and apportionment of foreign income taxes.

* * * * *

(d) * * *
(3) * * *
(v) * * *
(E) * * *

(6) *Reattribution asset.* The term *reattribution asset* means an asset that

produces one or more items of gross income, computed under Federal income tax law, to which a disregarded payment, other than a disregarded payment received in exchange for property, is allocated under the rules of paragraph (d)(3)(v)(B)(2) of this section.

* * * * *

(i) *Applicability dates.* (1) Except as provided in paragraphs (i)(2) through (4) of this section, this section applies to taxable years beginning after December 31, 2019.

(2) Paragraphs (b)(19) and (23) and (d)(3)(i), (ii), and (v) of this section apply to taxable years that begin after December 31, 2019, and end on or after November 2, 2020.

(3) Paragraph (d)(3)(v)(E)(6) of this section applies to taxable years that end on or after [date the final rule is filed with the **Federal Register**]. Taxpayers may choose to apply the rules in paragraph (d)(3)(v)(E)(6) of this section to taxable years beginning after December 31, 2019, and ending before [date the final rule is filed with the **Federal Register**], provided they apply paragraph (d)(3)(v)(E)(6) of this section consistently to their first taxable year beginning after December 31, 2019, and any subsequent taxable year beginning before [date the final rule is filed with the **Federal Register**]. Otherwise, for taxable years beginning after December 31, 2019, and ending before [date the final rule is filed with the **Federal Register**], see § 1.861–20(d)(3)(v)(E)(6) as contained in 26 CFR part 1 revised as of July 27, 2022.

(4) Paragraph (h) of this section applies to taxable years beginning after December 28, 2021.

■ **Par 3.** Section 1.901–2 is amended:

■ 1. By revising paragraph (b)(4)(i)(A).

■ 2. By redesignating paragraphs (b)(4)(i)(B), (b)(4)(i)(C)(3), and (b)(4)(i)(D) as paragraph (b)(4)(i)(G), (b)(4)(i)(D), and (b)(4)(i)(E), respectively.

■ 3. By adding new paragraph (b)(4)(i)(B).

■ 4. By revising paragraph (b)(4)(i)(C).

■ 5. By revising the first sentence of newly redesignated paragraph (b)(4)(i)(D).

■ 6. By adding paragraph (b)(4)(i)(F).

■ 7. In newly redesignated paragraph (b)(4)(i)(G)(1), by removing the language “one or more significant costs and expenses” and adding the language “substantially all of each item of significant cost or expense” in its place.

■ 8. In paragraph (b)(4)(iv)(A)(2), by removing the language “significant costs and expenses” and adding the language “substantially all of each item of significant cost or expense” in its place.

■ 9. In paragraph (b)(4)(iv)(B)(2), by removing the language “(b)(4)(i)(B)(2)”

and adding the language “(b)(4)(i)(G)(2)” in its place.

■ 10. By removing and reserving paragraph (b)(4)(iv)(C).

■ 11. In paragraphs (b)(4)(iv)(D)(2) and (b)(4)(iv)(E)(2), by removing the language “(b)(4)(i)(C)(2)” and adding the language “(b)(4)(i)(F)(2)” in its place.

■ 12. By adding paragraphs (b)(4)(iv)(F) through (J).

■ 13. By revising paragraphs (b)(5)(i)(B)(2), (d)(1)(iii), and (h).

The revisions and additions read as follows:

§ 1.901–2 Income, war profits, or excess profits tax paid or accrued.

* * * * *

(b) * * *

(4) * * *

(i) * * *

(A) *In general.* A foreign tax satisfies the cost recovery requirement if the base of the tax is computed by reducing gross receipts (as described in paragraph (b)(3) of this section) to permit recovery of substantially all of each item of significant cost or expense (including each item of cost or expense related to the categories described in paragraph (b)(4)(i)(B)(2) of this section) attributable, under reasonable principles, to such gross receipts. See paragraph (b)(4)(i)(B) of this section for rules regarding the determination of what is a significant cost or expense, paragraph (b)(4)(i)(C) of this section for rules regarding the recovery of substantially all of an item, paragraph (b)(4)(i)(E) of this section for rules regarding principles for attributing costs and expenses to gross receipts, and paragraph (b)(4)(i)(F) of this section for exceptions to this rule. A foreign tax need not permit recovery of significant costs and expenses, such as certain personal expenses, that are not attributable, under reasonable principles, to gross receipts included in the foreign tax base. A foreign tax whose base is gross receipts, with no reduction for costs and expenses, satisfies the cost recovery requirement only if there are no significant costs and expenses described in paragraph (b)(4)(i)(B) of this section attributable to the gross receipts included in the foreign tax base. See paragraph (b)(4)(iv)(A) of this section (*Example 1*). A foreign tax that provides an alternative cost allowance satisfies the cost recovery requirement only as provided in paragraph (b)(4)(i)(G) of this section.

(B) *Significant costs and expenses—*

(1) *In general.* Except as provided in paragraph (b)(4)(i)(B)(2) of this section, whether an item of cost or expense is significant for purposes of this paragraph (b)(4)(i) is determined based

on whether, for all taxpayers in the aggregate to which the foreign tax applies, the item of cost or expense constitutes a significant portion of the taxpayers' total costs and expenses.

(2) *Per se significant costs and expenses.* An item of cost or expense (as characterized under foreign law) related to capital expenditures, interest, rents, royalties, wages or other payments for services, and research and experimentation is always treated as an item of significant cost or expense for purposes of this paragraph (b)(4)(i).

(C) *Recovery of substantially all of each item—(1) In general.* Whether a foreign tax permits recovery of substantially all of each item of significant cost or expense is determined based solely on the terms of the foreign tax law.

(2) *Safe harbor.* One or more disallowances of a stated portion of an item (or multiple items) of significant cost or expense does not prevent a foreign tax from being considered to permit recovery of substantially all of each item of significant cost or expense if the total portion of the item (or items) that is disallowed does not exceed 25 percent. A limitation that caps the recovery of an item of significant cost or expense, or multiple items of cost or expense that relate to a single category of significant costs and expenses described in paragraph (b)(4)(i)(B)(2) of this section does not prevent a foreign tax from being considered to permit recovery of substantially all of each item of significant cost or expense if the limitation is a qualifying cap. For such purpose, a limitation that caps the recovery at a stated portion of gross receipts, gross income, or a similar measure is a qualifying cap if the stated portion of such measure is not less than 15 percent. A limitation that caps the recovery at a stated portion of taxable income (determined without regard to the item at issue) or a similar measure is a qualifying cap if the stated portion of such measure is not less than 30 percent.

(3) *Non-recovery of significant costs and expenses.* Significant costs and expenses (such as interest expense) are not considered to be recovered by reason of the time value of money attributable to the acceleration of a tax benefit or economic benefit attributable to the timing of the recovery of other costs and expenses (such as the current expensing of debt-financed capital expenditures).

(D) * * * A foreign tax law permits recovery of substantially all of each item of significant cost or expense even if such item of cost or expense is recovered earlier or later than it is

recovered under the Internal Revenue Code unless the time of recovery is so much later as effectively to constitute a denial of such recovery. * * *

* * * * *

(F) *Exceptions—(1) Disallowances consistent with U.S. principles.* Notwithstanding paragraph (b)(4)(i)(A) of this section, a disallowance of all or a portion of an item of significant cost or expense does not prevent a foreign tax from satisfying the cost recovery requirement if such disallowance is consistent with any principle underlying the disallowances required under the income tax provisions of the Internal Revenue Code, including the principles of limiting base erosion or profit shifting and addressing non-tax public policy concerns similar to those reflected in the Internal Revenue Code. For example, a foreign tax may satisfy the cost recovery requirement even if the foreign tax law disallows deductions in connection with hybrid transactions, disallows deductions attributable to gross receipts that in whole or in part are excluded, exempt or eliminated from taxable income, or disallows certain deductions consistent with non-tax public policy considerations similar to those underlying the disallowances contained in section 162. See paragraphs (b)(4)(iv)(I) and (J) of this section (*Examples 9 and 10*).

(2) *Amounts that need not be recovered.* A foreign tax law may satisfy the cost recovery requirement even if the foreign tax law does not permit recovery of costs and expenses attributable to wage income or to investment income that is not derived from a trade or business. In addition, in determining whether a foreign tax (the “tested foreign tax”) meets the cost recovery requirement, it is immaterial whether the tested foreign tax allows a deduction for other taxes that would qualify as foreign income taxes (determined without regard to whether such other tax allows a deduction for the tested foreign tax). See paragraphs (b)(4)(iv)(D) and (E) of this section (*Examples 4 and 5*).

* * * * *

(iv) * * *

(F) *Example 6: Substantially all; application of the safe harbor—(1) Facts.* Country X imposes a tax (“Country X tax”) on the income of corporations that are resident in Country X. Under Country X tax law, full deductions are allowed for each item of significant cost or expense attributable under reasonable principles to the gross receipts included in the Country X tax base, except that Country X tax law disallows a deduction for 25 percent of a taxpayer's costs and expenses for royalties related to patents.

(2) *Analysis.* Under paragraph (b)(4)(i)(B)(2) of this section, an item of cost or expense related to royalties is always treated as a significant cost or expense, and therefore, under paragraph (b)(4)(i)(A) of this section, absent an exception, Country X tax law must permit recovery of substantially all of each item of cost or expense related to royalties, including the item of royalties related to patents. The stated percentage of costs and expenses from royalties related to patents (25 percent) that is disallowed under Country X tax law does not exceed 25 percent. Accordingly, under the safe harbor in paragraph (b)(4)(i)(C)(2) of this section, the disallowance does not prevent the Country X tax from being considered to permit recovery of substantially all of each item of cost or expense related to royalties, and therefore the Country X tax satisfies the cost recovery requirement.

(G) *Example 7: Substantially all; application of the safe harbor—(1) Facts.* Country X imposes a tax (“Country X tax”) on the income of corporations that are resident in Country X. Under Country X tax law, full deductions are allowed for each item of significant cost or expense attributable under reasonable principles to the gross receipts included in the Country X tax base, except that Country X tax law disallows a deduction for 15 percent of a taxpayer's costs and expenses for rents and 25 percent of a taxpayer's costs and expenses for interest.

(2) *Analysis.* Under paragraph (b)(4)(i)(B)(2) of this section, an item of cost or expense related to rents or interest is always treated as a significant cost or expense, and therefore, under paragraph (b)(4)(i)(A) of this section, absent an exception, Country X tax law must permit recovery of substantially all of each item of cost or expense related to royalties and interest. The stated percentage of the costs and expenses related to rents (15 percent) that is disallowed under Country X tax law does not exceed 25 percent. Additionally, the stated percentage of the costs and expenses related to interest (25 percent) that is disallowed under Country X law does not exceed 25 percent. Accordingly, under the safe harbor in paragraph (b)(4)(i)(C)(2) of this section, the disallowances do not prevent the Country X tax from being considered to permit recovery of substantially all of each item of cost or expense related to rents and interest, and therefore the Country X tax satisfies the cost recovery requirement.

(H) *Example 8: Substantially all; application of the safe harbor—(1) Facts.* Country X imposes a tax (“Country X tax”) on the income of corporations that are resident in Country X. Under Country X tax law, full deductions are allowed for each item of significant cost or expense attributable under reasonable principles to the gross receipts included in the Country X tax base, except that Country X tax law caps the recovery of the deduction of interest at 30 percent of the taxpayer's taxable income determined without regard to interest expense.

(2) *Analysis.* Under paragraph (b)(4)(i)(B)(2) of this section, an item of cost or expense related to interest is always

treated as a significant cost or expense, and therefore, under paragraph (b)(4)(i)(A) of this section, absent an exception, Country X tax law must permit recovery of substantially all of each item of cost or expense related to interest. The stated cap on recovery in Country X tax law with respect to interest (30 percent of taxable income determined without regard to interest expense) is not less than 30 percent of taxable income determined without regard to interest expense. Additionally, the cap on recovery relates to a single category of significant costs and expenses described in paragraph (b)(4)(i)(B)(2) of this section. Accordingly, under the safe harbor in paragraph (b)(4)(i)(C)(2) of this section, the disallowance does not prevent the Country X tax from being considered to permit recovery of substantially all of each item of cost or expense related to interest, and therefore the Country X tax satisfies the cost recovery requirement.

(I) *Example 9: Permissible disallowance based on U.S. principles—(1) Facts.* Country X imposes a tax on the income of corporations that are resident in Country X. Under Country X tax law, full deductions are allowed for each item of significant cost or expense attributable under reasonable principles to the gross receipts included in the Country X tax base, except that under Country X's anti-hybrid rules, a deduction is disallowed for any payment, including interest, royalties, rents, or payments for services, made by a Country X resident to a related entity located outside of Country X if the payment is not included in gross income by the payee or the payee is not subject to tax.

(2) *Analysis.* Under paragraph (b)(4)(i)(B)(2) of this section, each item of cost or expense related to interest, rents, royalties, and payments for services is always treated as a significant cost or expense, and therefore, under paragraph (b)(4)(i)(A) of this section, absent an exception, Country X tax law must permit recovery of substantially all of each item of cost or expense related to interest, rents, royalties, and payments for services. Country X tax law does not permit recovery of any portion of any item of significant cost or expense that is subject to the anti-hybrid rules. As a result, the safe harbor in paragraph (b)(4)(i)(C)(2) of this section does not apply to such item. Further, because a deduction is disallowed for any item of cost or expense that is subject to the Country X anti-hybrid rules, the Country X tax law completely disallows certain items of cost and expense related to interest, rents, royalties, and payments for services and thus does not permit recovery of substantially all of each item of significant cost or expense related to interest, rents, royalties, and payments for services. However, under paragraph (b)(4)(i)(F)(1) of this section, a disallowance of all or a portion of an item of significant cost or expense does not prevent a foreign tax from satisfying the cost recovery requirement if the disallowance is consistent with any principle underlying the disallowances required under the income tax provisions of the Internal Revenue Code. The income tax provisions of the Internal Revenue Code, specifically section 267A,

contain disallowances of deductions based on the principle of limiting base erosion or profit shifting. Country X's disallowance of deductions for any payment, including interest, royalties, rents, or payments for services also reflects the principle of limiting base erosion or profit shifting. Accordingly, because Country X's anti-hybrid rules are consistent with the principle of limiting base erosion or profit shifting, the Country X tax satisfies the cost recovery requirement.

(J) *Example 10: Permissible disallowance based on U.S. principles—(1) Facts.* Country X imposes a tax on the income of corporations that are resident in Country X. Under Country X tax law, full deductions are allowed for each item of significant cost or expense attributable to the gross receipts included in the Country X tax base, except that no deduction is permitted for any stock-based payments for services.

(2) *Analysis.* Under paragraph (b)(4)(i)(B)(2) of this section, each item of cost or expense related to wages or other payments for services is always treated as a significant cost or expense, and therefore, under paragraph (b)(4)(i)(A) of this section, absent an exception, Country X tax law must permit recovery of substantially all of each item of cost or expense related to wages or other payments for services. Country X tax law denies a deduction for any stock-based payments for services, and therefore the safe harbor in paragraph (b)(4)(i)(C)(2) of this section is not satisfied. Further, given that no deduction is allowed for stock-based payments for services, the Country X tax law completely disallows an item of cost or expense related to wages or other payments for services and thus does not permit recovery of substantially all of each item of significant cost or expense related to wages or other payments for services. However, under paragraph (b)(4)(i)(F)(1) of this section, a disallowance of all or a portion of an item of significant cost or expense does not prevent a foreign tax from satisfying the cost recovery requirement if such disallowance is consistent with any principle underlying the disallowances required under the income tax provisions of the Internal Revenue Code. The income tax provisions of the Internal Revenue Code contain targeted disallowances or limits on the deductibility of certain items of compensation in particular circumstances based on non-tax public policy reasons, including to influence the amount or use of a certain type of compensation in the labor market. For example, section 162(m) imposes limits on deductions for compensation of certain highly-paid employees, and section 280G limits the deductibility of certain "parachute payments" provided to individuals when an entity undergoes a change of control. Country X's targeted disallowance of deductions for the portion of payments for services attributable to stock-based compensation also reflects a principle of influencing the amount or use of a certain type of compensation (stock-based compensation) in the labor market. Accordingly, because the Country X tax law's disallowance is consistent with a principle underlying the disallowances required under the income tax provisions of the Internal Revenue Code, the Country X tax satisfies the cost recovery requirement.

(5) * * *
(i) * * *
(B) * * *

(2) *Royalties.* Under the foreign tax law, gross income from royalties must be sourced based on the place of use of, or the right to use, the intangible property, as determined under reasonable principles (which do not include determining the place of use of, or the right to use, the intangible property based on the location of the payor).

* * * * *

(d) * * *
(1) * * *

(iii) *Tax imposed on nonresidents—(A) In general.* A foreign levy imposed on nonresidents is always treated as a separate levy from that imposed on residents, even if the base of the tax as applied to residents and nonresidents is the same, and even if the levies are treated as a single levy under foreign tax law.

(B) *Withholding tax—(1) In general.* Except as otherwise provided in this paragraph (d)(1)(iii)(B), a withholding tax (as defined in section 901(k)(1)(B)) that is imposed on a payment giving rise to gross income of nonresidents is treated as a separate levy as to each separate class of income described in section 61 (for example, interest, dividends, rents, or royalties) subject to the withholding tax.

(2) *Subsets of income.* If two or more subsets of a separate class of income are subject to a withholding tax based on different income attribution rules (for example, if technical services are subject to tax based on the residence of the payor and other services are subject to tax based on where the services are performed), separate levies are considered to be imposed with respect to each subset of that separate class of income.

(3) *Royalty income.* A withholding tax that is imposed on a payment giving rise to gross royalty income of a nonresident that is made pursuant to a single-country license (as determined under § 1.903–1(c)(2)(iv)) is treated as a separate levy from a withholding tax that is imposed on other gross royalty income of such nonresident and is also treated as a separate levy from any withholding tax imposed on other nonresidents.

* * * * *

(h) *Applicability dates—(1) In general.* Except as provided in paragraphs (h)(2) and (3) of this section, this section applies to foreign taxes paid (within the meaning of paragraph (g) of this section) in taxable years beginning on or after December 28, 2021. For foreign taxes

that relate to (and if creditable are considered to accrue in) taxable years beginning before December 28, 2021, and that are remitted in taxable years beginning on or after December 28, 2021, by a taxpayer that accounts for foreign income taxes on the accrual basis, *see* § 1.901–2 as contained in 26 CFR part 1 revised as of April 1, 2021.

(2) *Certain foreign taxes paid to Puerto Rico.* For foreign taxes paid to Puerto Rico by reason of section 1035.05 of the Puerto Rico Internal Revenue Code of 2011, as amended (13 L.P.R.A. 30155) (treating certain income, gain or loss as effectively connected with the active conduct of a trade or business with Puerto Rico), this section applies to foreign taxes paid (within the meaning of paragraph (g) of this section) in taxable years beginning on or after January 1, 2023. For foreign taxes described in the preceding sentence that are paid in taxable years beginning before January 1, 2023, *see* § 1.901–2 as contained in 26 CFR part 1 revised as of April 1, 2021.

(3) *Modifications to cost recovery and royalty attribution rules.* Paragraphs (b)(4)(i) and (iv), (b)(5)(i)(B)(2), and (d)(1)(iii) of this section apply to foreign taxes paid (within the meaning of paragraph (g) of this section) in taxable years ending on or after November 18, 2022. For foreign taxes described in the preceding sentence that are paid in taxable years ending before November 18, 2022, *see* § 1.901–2(b)(4)(i) and (iv), (b)(5)(i)(B)(2), and (d)(1)(iii) as contained in 26 CFR part 1 revised as of July 27, 2022. Taxpayers may choose to apply the rules in paragraphs (b)(4)(i) and (iv) of this section to foreign taxes paid in taxable years beginning on or after December 28, 2021, and ending before November 18, 2022 provided that they consistently apply those rules to such taxable years. Additionally, taxpayers may choose to apply the rules of paragraphs (b)(5)(i)(B)(2) and (d)(1)(iii) of this section to foreign taxes paid in taxable years beginning on or after December 28, 2021, and ending before November 18, 2022, provided that they consistently apply those rules and the rules of § 1.903–1(c)(2) and (d)(3), (4), and (8) through (11) to such taxable years.

* * * * *

■ **Par 4.** Section 1.903–1 is amended:

- 1. By revising paragraphs (c)(2) introductory text and (c)(2)(iii).
- 2. By adding paragraph (c)(2)(iv).
- 3. By revising paragraph (d)(3).
- 4. By removing and reserving paragraph (d)(4).
- 5. By adding paragraphs (d)(8) through (11).

■ 6. By revising paragraph (e).

The revisions and additions read as follows:

§ 1.903–1 Taxes in lieu of income taxes.

* * * * *

(c) * * *

(2) *Covered withholding tax.* A tested foreign tax is a covered withholding tax if, based on the foreign tax law (except as provided in paragraph (c)(2)(iii)(B) of this section), the requirements in paragraphs (c)(1)(i) and (c)(2)(i) through (iii) of this section are met with respect to the tested foreign tax. *See also* § 1.901–2(d)(1)(iii) for rules treating withholding taxes as separate levies with respect to each class of income subject to the tax, with respect to each subset of a class of income that is subject to different income attribution rules, or with respect to withholding tax that is imposed on a payment giving rise to gross royalty income of a nonresident that is made pursuant to a single-country license (as determined under paragraph (c)(2)(iv) of this section).

* * * * *

(iii) *Source-based attribution requirement.* The income subject to the tested foreign tax satisfies the requirements in paragraph (c)(2)(iii)(A) or (B) of this section.

(A) The income subject to the tested foreign tax satisfies the attribution requirement described in § 1.901–2(b)(5)(i)(B).

(B) The income subject to the tested foreign tax is characterized as royalty income and the payment giving rise to such income is made pursuant to a single-country license as determined under paragraph (c)(2)(iv) of this section. For purposes of this paragraph (c)(2)(iii)(B) and paragraph (c)(2)(iv) of this section, whether the income is characterized as royalty income is determined under the foreign tax law, except that income from the sale of a copyrighted article (as determined under rules similar to § 1.861–18) is not characterized as royalty income regardless of the characterization of the income under the foreign tax law.

(iv) *Single-country license—(A) In general.* Except as otherwise provided in this paragraph (c)(2)(iv), for purposes of paragraph (c)(2)(iii)(B) of this section, a payment is made pursuant to a single-country license if the terms of the license agreement pursuant to which the payment is made characterize the payment as a royalty and limit the territory of the license to the foreign country imposing the tested foreign tax.

(B) *Separately stated portions.* If a written agreement that is not described in paragraph (c)(2)(iv)(A) of this section separately states a portion (whether as a

specified amount or as a formula) of the payment subject to the tested foreign tax and such portion is both characterized as a royalty under the terms of the agreement and is attributable to the part of the territory of the license that is solely within the foreign country imposing the tested foreign tax, then that portion of the payment is treated as made pursuant to a single-country license.

(C) *Validity of agreement.* A payment is considered not made pursuant to a single-country license if the taxpayer knows, or has reason to know, that the terms of the agreement pursuant to which the payment is made misstate the territory in which the relevant intangible property is used or overstate the amount of the royalty with respect to the part of the territory of the license that is solely within the foreign country imposing the tested foreign tax. A taxpayer is considered to have reason to know if its knowledge of relevant of facts or circumstances is such that a reasonably prudent person in the position of the taxpayer would question whether the terms of the agreement misstate the territory in which the relevant intangible property is used or overstate the amount of a royalty. For purposes of this section, the principles of sections 482 and 861 apply to determine whether the terms of the agreement misstate the territory in which the relevant intangible property is used or overstate the amount of a royalty. *See* paragraph (d)(11) of this section (*Example 11*).

(D) *Documentation.* A taxpayer must provide the agreement described in paragraph (c)(2)(iv)(A) or (B) of this section, as applicable (the “required agreement”), within 30 days of a request by the Commissioner or another period as agreed between the Commissioner and the taxpayer. Except as provided in the next sentence, the required agreement pursuant to which the royalty is paid must be executed no later than the date of payment that gives rise to the gross royalty income that is subject to the tested foreign tax. In the case of a royalty that is paid before the date on which the required agreement is executed, in order to meet the requirement of this paragraph (c)(2)(iv)(D), the required agreement must be executed no later than May 17, 2023, and the agreement must state that royalties paid on or before the date of execution of the agreement are, for purposes of this paragraph (c)(2)(iv), considered paid pursuant to the terms of the agreement.

(d) * * *

(3) *Example 3: Withholding tax on royalties; attribution requirement*—(i) *Facts.* YCo, a resident of Country Y, is a controlled foreign corporation wholly owned by USP, a domestic corporation. In Year 1, YCo enters into a written license agreement (the “Agreement”) with XCo, a resident of Country X unrelated to YCo or USP, for the right to use YCo’s intangible property (“IP”) in a territory defined by the Agreement as the entire world, including Country X, in exchange for payments that the terms of the Agreement characterize as royalties. The payments made by XCo to YCo under the Agreement are also characterized as royalties under the laws of Country X. Under Country X’s tax law, all gross royalty payments made by a Country X resident to a nonresident are treated as giving rise to Country X source income and are subject to a 20 percent withholding tax, regardless of whether the nonresident payee has a taxable presence in Country X. Country X has a generally-imposed net income tax within the meaning of paragraph (c)(1)(i) of this section, and nonresidents subject to the withholding tax on royalties are not also subject to a Country X net income tax on their royalty income. In Year 1, XCo withholds 20u (units of Country X currency) of tax on a 100u royalty paid to YCo under the Agreement.

(ii) *Analysis*—(A) *Separate levy.* Under § 1.901–2(d)(1)(iii)(B)(1), Country X’s withholding tax imposed on gross royalty income of nonresidents is treated as a separate levy. Under § 1.901–2(d)(1)(iii)(B)(3), the 20u of Country X withholding tax imposed on the 100u of royalties paid by XCo to YCo is treated as a separate levy from the Country X withholding tax on royalties if the Agreement pursuant to which the royalties are paid is a single-country license under paragraph (c)(2)(iv) of this section. The Agreement does not meet the requirements of paragraph (c)(2)(iv) of this section because it neither limits the territory of the license to Country X nor separately states the portion of the payment that is with respect to the part of the territory of the license that is solely within Country X. Thus, the 20u of Country X withholding tax paid by YCo is not treated as a separate levy under § 1.901–2(d)(1)(iii)(B)(3).

(B) *Covered withholding tax.* Under paragraph (c)(2) of this section, a tested foreign tax is a covered withholding tax if paragraphs (c)(1)(i) and (c)(2)(i) through (iii) of this section are met. Country X’s withholding tax on royalties meets the requirements of paragraphs (c)(1)(i) and (c)(2)(i) and (ii) of this section because Country X has a generally-imposed net income tax, Country X’s withholding tax on the royalties paid pursuant to the Agreement is imposed on the gross royalty income of persons who are nonresidents of Country X, and nonresidents subject to the withholding tax on royalties are not also subject to the Country X generally-imposed net income tax on their royalty income. However, the Country X withholding tax on royalties paid pursuant to the Agreement does not meet the requirements of § 1.901–2(b)(5)(i)(B) and paragraph (c)(2)(iii)(A) of this section because Country X’s sourcing rule for royalties (based

on residence of the payor) is not based on the place of use of, or the right to use, the intangible property. Additionally, the payment that is subject to Country X’s withholding tax is not made pursuant to a single-country license under paragraph (c)(2)(iv) of this section for the reasons described in paragraph (d)(3)(ii)(A) of this section (the separate levy analysis of this paragraph (d)(3) (*Example 3*)). Therefore, the requirement in paragraph (c)(2)(iii)(B) of this section is not met. Accordingly, the Country X withholding tax paid by YCo is not a covered withholding tax, and none of the 20u Country X withholding tax paid by YCo with respect to the 100u royalty payment made to XCo is a foreign income tax.

* * * * *

(8) *Example 8: Withholding tax on royalties; single-country license*—(i) *Facts.* The facts are the same as in paragraph (d)(3)(i) of this section (the facts of *Example 3*) except that in Year 1, YCo enters into a written license agreement (the “Agreement”) with XCo for the right to use YCo’s IP in a territory defined by the Agreement as Country X, in exchange for payments that the terms of the Agreement characterize as royalties, and XCo in fact only uses the IP in Country X. In Year 1, XCo withholds 20u of tax from 100u of royalties paid to YCo under the Agreement.

(ii) *Analysis*—(A) *Separate levy.* Under § 1.901–2(d)(1)(iii)(B)(1), Country X’s withholding tax imposed on gross royalty income of nonresidents is treated as a separate levy. Under § 1.901–2(d)(1)(iii)(B)(3), the 20u of Country X withholding tax imposed on the 100u of royalties paid by XCo to YCo is treated as a separate levy from the Country X withholding tax on royalties if the Agreement pursuant to which the royalties are paid is a single-country license under paragraph (c)(2)(iv) of this section. The Agreement meets the requirements of paragraph (c)(2)(iv)(A) of this section because it is a written license agreement that characterizes the payment as a royalty and limits the territory of the license to Country X. Thus, the 20u Country X withholding tax paid by YCo is treated as a separate levy under § 1.901–2(d)(1)(iii)(B)(3).

(B) *Covered withholding tax.* Under paragraph (c)(2) of this section, a tested foreign tax is a covered withholding tax if paragraphs (c)(1)(i) and (c)(2)(i) through (iii) of this section are met. Country X has a generally-imposed net income tax, Country X’s withholding tax on the royalties paid pursuant to the Agreement is a withholding tax that is imposed on the gross income of persons who are nonresidents of Country X, and nonresidents subject to the withholding tax on royalties paid pursuant to the Agreement are not also subject to a net income tax on their royalty income. Thus, the requirements of paragraphs (c)(1)(i) and (c)(2)(i) and (ii) of this section are met. The withholding tax paid by YCo does not meet the requirements of § 1.901–2(b)(5)(i)(B) and paragraph (c)(2)(iii)(A) of this section because Country X’s source rule for royalties (based on residence of the payor) is not based on the place of use of, or the right to use, the intangible property. However, the payment

that is subject to Country X’s withholding tax is made pursuant to a single-country license under paragraph (c)(2)(iv) of this section for the reasons described in paragraph (d)(8)(ii)(A) of this section (the separate levy analysis of this *Example 8*). Therefore, the requirement in paragraph (c)(2)(iii)(B) of this section is met. Accordingly, the Country X withholding tax on the payment made by XCo to YCo pursuant to the Agreement is a covered withholding tax and all of the 20u of Country X withholding tax paid by YCo with respect to the 100u of royalties under the Agreement is a foreign income tax.

(9) *Example 9: Withholding tax on royalties; separately stated portion*—(i) *Facts.* The facts are the same as in paragraph (d)(3)(i) of this section (the facts of *Example 3*) except that in Year 1, YCo enters into a written agreement (the “Agreement”) with XCo for the right to use YCo’s IP in a territory defined by the Agreement as the entire world, as well as for YCo to provide certain services to XCo in Country Y, in exchange for a payment equal to 10 percent of XCo’s annual revenue. The Agreement provides a formula for determining the amount of the payment that is characterized as a royalty and that is with respect to the part of the territory that is within Country X (the “separately stated formula”). The separately stated formula provides that the first 30u of the payment represents payment for services provided by YCo, and that 40 percent of the remainder of the payment represents payment of a royalty with respect to the part of the territory of the license that is solely within Country X. The portion of the payment by XCo to YCo that is characterized as services income under the Agreement is also characterized as services income under the laws of Country X. Additionally, all payments by a resident of Country X for services provided by a nonresident are treated as giving rise to Country X source income, regardless of where the services are performed, and gross income from services is subject to the same 20 percent withholding tax as gross royalty income. In Year 1, XCo earns gross income of 1,800u and pays YCo 180u under the Agreement. XCo withholds 12u of tax from the 60u of royalties attributable to the part of the territory of the license that is solely within Country X that are paid to YCo under the separately stated formula in the Agreement. The portion of the payment by XCo to YCo that is characterized as a royalty with respect to the part of the territory of the license that is solely within Country X under the separately stated formula in the Agreement is also characterized as a royalty under the laws of Country X. XCo withholds 24u of tax from the remaining 120u payment paid to YCo under the Agreement, consisting of 6u of tax on the 30u payment for services and 18u of tax on 90u of royalties. YCo does not know, or have reason to know, that the terms of the Agreement misstate the territory in which YCo’s IP is used or overstate the amount of the royalty with respect to the part of the territory of the license that is solely within Country X.

(ii) *Analysis*—(A) *Separately stated portion.* The analysis is the same as in paragraph (d)(8)(ii) of this section (the

analysis of *Example 8*), except that the portion of the payment that is a royalty with respect to the part of the territory of the license that is solely within Country X under the separately stated formula in the Agreement is treated as made pursuant to a single-country license under paragraph (c)(2)(iv) of this section because the Agreement is a written agreement that separately states the portion of the payment that is characterized as a royalty and that is with respect to the part of the territory of the license that is solely within Country X. Thus, the Country X withholding tax on the portion of the payment from XCo to YCo that is a payment of a royalty with respect to the part of the territory of the license that is solely within Country X under the separately stated formula under the Agreement is a separate levy and a covered withholding tax. Accordingly, the 12u Country X withholding tax paid by YCo from the 60u of royalties with respect to the part of the territory of the license that is solely within Country X is a foreign income tax.

(B) *Remaining portion of royalties.* The analysis is the same as paragraph (d)(3)(ii) of this section (the analysis of *Example 3*). Specifically, the 18u Country X withholding tax on the 90u royalty payment that is not with respect to the part of the territory that is within Country X is neither a separate levy nor a covered withholding tax. Accordingly, none of the 18u Country X withholding tax paid by YCo with respect to the remaining 90u royalty payment under the Agreement is a payment of foreign income tax.

(C) *Services portion.* Under § 1.901–2(d)(1)(iii)(B)(1), Country X's withholding tax imposed on gross services income of nonresidents is a separate levy. The Country X withholding tax of 6u on the 30u payment for services made by XCo to YCo under the Agreement is not a covered withholding tax. The withholding tax paid by YCo does not meet the requirements of § 1.901–2(b)(5)(i)(B) and paragraph (c)(2)(iii)(A) of this section because Country X's sourcing rule for services (based on residence of the payor) is not reasonably similar to the sourcing rule that applies under the Internal Revenue Code (based on where the services are performed). The special separate levy and covered withholding tax rules for single-country licenses under § 1.901–2(d)(1)(iii)(B)(3) and paragraph (c)(2)(iii)(B) of this section do not apply to withholding taxes on payments for services. Accordingly, none of the 6u of Country X withholding tax paid by YCo with respect to the 30u payment for services under the Agreement is a payment of foreign income tax.

(10) *Example 10: Characterization of payment—(i) Facts.* The facts are the same as in paragraph (d)(3)(i) of this section (the facts of *Example 3*), except that in Year 1, YCo enters into a written license agreement (the “Agreement”) with XCo for the right to use YCo's IP in a territory defined by the Agreement as Country X, in exchange for a payment that the terms of the Agreement characterize as a royalty, but that is characterized as a payment for services under the laws of Country X, and all payments of services paid by a resident of Country X to a nonresident are treated as giving rise to

Country X source income, regardless of where the services are performed, and are subject to a 20 percent withholding tax.

(ii) *Analysis.* Under § 1.901–2(d)(1)(iii)(B)(1), Country X's withholding tax imposed on gross services income of nonresidents is a separate levy. The Country X withholding tax of 20u on the 100u payment for services made by XCo to YCo under the Agreement is not a covered withholding tax. The withholding tax paid by YCo does not meet the requirements of § 1.901–2(b)(5)(i)(B) and paragraph (c)(2)(iii)(A) of this section because Country X's sourcing rule for services (based on residence of the payor) is not reasonably similar to the sourcing rule that applies under the Internal Revenue Code (based on where the services are performed). The special separate levy and covered withholding tax rules for single-country licenses under § 1.901–2(d)(1)(iii)(B)(3) and paragraph (c)(2)(iii)(B) of this section do not apply to withholding taxes on income that is not characterized as royalty income under the foreign tax law. Accordingly, none of the 20u Country X withholding tax paid by YCo with respect to the 100u paid under the Agreement is a payment of foreign income tax.

(11) *Example 11: Withholding tax on royalties, validity of agreement—(i) Facts.* The facts are the same as in paragraph (d)(3)(i) of this section (the facts of *Example 3*), except that XCo is a controlled foreign corporation wholly owned by USP.

Additionally, in Year 2, XCo and YCo cancel the written license agreement entered into in Year 1 and YCo enters into two new written license agreements with XCo, one agreement which grants XCo the right to use certain YCo IP in a territory defined as Country X (the “Country X Agreement”), and one of which grants XCo the right to use the same YCo IP in a territory defined as the entire world except for Country X (the “Rest of World Agreement”). Both agreements characterize the payments under the agreements as royalties, and the payments are also characterized as royalties under the laws of Country X. In Year 2, XCo withholds a total of 20u of tax from a total of 100u of royalties paid to YCo under the Country X Agreement and the Rest of World Agreement. Based on the terms of each agreement, 18u of tax was withheld from 90u of royalties paid to YCo under the Country X Agreement, and 2u of tax from 10u of royalties paid to YCo under the Rest of World Agreement. YCo knew or had reason to know that under the principles of sections 482 and 861, with respect to the 100u of royalties paid by XCo to YCo, 40u is attributable to XCo's use of YCo IP in Country X and 60u is attributable to use of YCo IP outside Country X.

(ii) *Analysis—(A) Rest of World Agreement.* The analysis is the same as paragraph (d)(3)(ii) of this section (the analysis of *Example 3*). Specifically, the 2u Country X withholding tax on the 10u royalty payment under the Rest of World Agreement is neither a separate levy nor a covered withholding tax. Accordingly, none of the 2u Country X withholding tax paid by YCo with respect to the 10u royalty payment under the Rest of World Agreement is a payment of foreign income tax.

(B) *Country X Agreement.* The analysis is the same as paragraph (d)(3)(ii) of this section (the analysis of *Example 3*), except that the reason that the Country X Agreement does not meet the requirements of paragraph (c)(2)(iv) of this section is that YCo knew or had reason to know that the terms of the Country X Agreement overstate the amount of the royalty with respect to Country X. Thus, the 18u Country X withholding tax on the 90u royalty payment under the Country X Agreement is neither a separate levy nor a covered withholding tax. Accordingly, none of the 18u Country X withholding tax paid by YCo with respect to the 90u royalty payment under the Country X Agreement is a payment of foreign income tax.

(e) *Applicability dates—(1) In general.* Except as provided in paragraphs (e)(2) and (3) of this section, this section applies to foreign taxes paid (within the meaning of § 1.901–2(g)) in taxable years beginning on or after December 28, 2021. For foreign taxes that relate to (and if creditable are considered to accrue in) taxable years beginning before December 28, 2021, and that are remitted in taxable years beginning on or after December 28, 2021, by a taxpayer that accounts for foreign income taxes on the accrual basis, see § 1.903–1 as contained in 26 CFR part 1 revised as of April 1, 2021.

(2) *Certain foreign taxes paid to Puerto Rico.* For foreign taxes paid to Puerto Rico under section 3070.01 of the Puerto Rico Internal Revenue Code of 2011, as amended (13 L.P.R.A. 31771) (imposing an excise tax on a controlled group member's acquisition from another group member of certain personal property manufactured or produced in Puerto Rico and certain services performed in Puerto Rico), this section applies to foreign taxes paid (within the meaning of § 1.901–2(g)) in taxable years beginning on or after January 1, 2023. For foreign taxes described in the preceding sentence that are paid in taxable years beginning before January 1, 2023, see § 1.903–1 as contained in 26 CFR part 1 revised as of April 1, 2021.

(3) *Modifications to the covered withholding tax rules.* Paragraphs (c)(2) and (d)(3), (4), and (8) through (11) of this section apply to foreign taxes paid (within the meaning of § 1.901–2(g)) in taxable years ending on or after November 18, 2022. For foreign taxes that are paid in taxable years ending before November 18, 2022, see § 1.903–1(c)(2) and (d)(3) and (4) as contained in 26 CFR part 1 revised as of July 27, 2022. Taxpayers may choose to apply the rules in paragraphs (c)(2) and (d)(3), (4), and (8) through (11) of this section to foreign taxes paid in taxable years beginning on or after December 28, 2021, and ending before November 18,

2022, provided that they consistently apply those rules and the rules of § 1.901–2(b)(5)(i)(B)(2) and (d)(1)(iii) to such taxable years.

Melanie R. Krause,

Acting Deputy Commissioner for Services and Enforcement.

[FR Doc. 2022–25337 Filed 11–18–22; 11:15 am]

BILLING CODE 4830–01–P

LIBRARY OF CONGRESS

Copyright Office

37 CFR Part 210

[Docket No. 2022–5]

Termination Rights and the Music Modernization Act's Blanket License

AGENCY: U.S. Copyright Office, Library of Congress.

ACTION: Notice of proposed rulemaking; extension of comment period.

SUMMARY: The U.S. Copyright Office is extending the deadline for the submission of written comments in response to its October 25, 2022 notice of proposed rulemaking regarding the applicability of the derivative works exception to termination rights under the Copyright Act to the statutory mechanical blanket license established under the Orrin G. Hatch–Bob Goodlatte Music Modernization Act.

DATES: The comment periods for the notice of proposed rulemaking published October 25, 2022, at 87 FR 64405, are extended. Written comments must be received no later than 11:59 p.m. Eastern Time on December 1, 2022. Written reply comments must be received no later than 11:59 p.m. Eastern Time on January 5, 2023.

ADDRESSES: For reasons of governmental efficiency, the Copyright Office is using the *regulations.gov* system for the submission and posting of public comments in this proceeding. All comments are therefore to be submitted electronically through *regulations.gov*. Specific instructions for submitting comments are available on the Copyright Office's website at <https://copyright.gov/rulemaking/mma-termination>. If electronic submission of comments is not feasible due to lack of access to a computer or the internet, please contact the Copyright Office using the contact information below for special instructions.

FOR FURTHER INFORMATION CONTACT:

Megan Efthimiadis, Assistant to the General Counsel, by email at meft@copyright.gov or telephone at 202–707–8350.

SUPPLEMENTARY INFORMATION: On October 25, 2022 the Office issued a notice of proposed rulemaking seeking public comments regarding the applicability of the derivative works exception to termination rights under the Copyright Act to the statutory mechanical blanket license established under the Orrin G. Hatch–Bob Goodlatte Music Modernization Act. 87 FR 64405 (October 25, 2022).

In light of the Thanksgiving and Christmas holidays, to ensure that members of the public have sufficient time to respond, and to ensure that the Office has the benefit of a complete record, the Office is extending the deadline for the submission of written comments to no later than 11:59 p.m. Eastern Time on December 1, 2022 and is extending the deadline for the submission of written reply comments to no later than 11:59 p.m. Eastern Time on January 5, 2023.

Dated: November 17, 2022.

Suzanne V. Wilson,

General Counsel and Associate Register of Copyrights.

[FR Doc. 2022–25447 Filed 11–21–22; 8:45 am]

BILLING CODE 1410–30–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[EPA–R04–OAR–2022–0433; FRL–10402–01–R4]

Air Plan Approval; North Carolina; Minor Revisions to Nitrogen Oxides Rule

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: The Environmental Protection Agency (EPA) is proposing to approve a revision to the North Carolina State Implementation Plan (SIP) submitted by the North Carolina Department of Environmental Quality (NCDEQ), Division of Air Quality, via a letter dated April 13, 2021, and received by EPA on April 14, 2021. This revision contains minor changes to North Carolina's nitrogen oxides (NO_x) rule. EPA is proposing to approve these changes pursuant to the Clean Air Act (CAA or Act).

DATES: Comments must be received on or before December 22, 2022.

ADDRESSES: Submit your comments, identified by Docket ID No. EPA–R04–OAR–2022–0433 at www.regulations.gov. Follow the online instructions for submitting comments.

Once submitted, comments cannot be edited or removed from *Regulations.gov*. EPA may publish any comment received to its public docket. Do not submit electronically any information you consider to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Multimedia submissions (audio, video, etc.) must be accompanied by a written comment. The written comment is considered the official comment and should include discussion of all points you wish to make. EPA will generally not consider comments or comment contents located outside of the primary submission (*i.e.*, on the web, cloud, or other file sharing system). For additional submission methods, the full EPA public comment policy, information about CBI or multimedia submissions, and general guidance on making effective comments, please visit www2.epa.gov/dockets/commenting-epa-dockets.

FOR FURTHER INFORMATION CONTACT:

Steven Scofield, Air Regulatory Management Section, Air Planning and Implementation Branch, Air and Radiation Division, U.S. Environmental Protection Agency, Region 4, 61 Forsyth Street SW, Atlanta, Georgia 30303–8960. The telephone number is (404) 562–9034. Mr. Scofield can also be reached via electronic mail at scofield.steve@epa.gov.

SUPPLEMENTARY INFORMATION:

I. What action is EPA proposing to take?

EPA is proposing to approve changes to North Carolina's SIP that were provided to EPA through NCDEQ via a letter dated April 13, 2021.¹ EPA is proposing to approve changes to North Carolina's 15A North Carolina Administrative Code (NCAC) Subchapter 02D, Section .1400, *Nitrogen Oxides* (hereinafter referred to as Section .1400).² The April 13, 2021, revision to the North Carolina SIP transmits changes that do not alter the meaning of the regulations, such as clarifying changes, updated cross-

¹ EPA notes that the submittal was received through the State Planning Electronic Collaboration System (SPECS) on April 14, 2021. For clarity, this notice will refer to the submittal by the date on the cover letter, which is April 13, 2021.

² The State submitted several revisions with the same April 13, 2021, cover letter following readoption, including revisions to rules in Section .1400. These revisions were submitted pursuant to North Carolina's 10-year readoption process at North Carolina General Statute at 150B–21–3A. EPA will be considering action on other SIP revisions submitted with the April 13, 2021, cover letter in separate rulemakings.

references, and several ministerial language changes.

II. EPA's Analysis of the State's Submittal

North Carolina's SIP revision contains minor changes to Section .1400.³ EPA has preliminarily determined that these changes do not interfere with attainment and maintenance of the national ambient air quality standards (NAAQS) or any other applicable requirement of the Act because they are minor in nature. For these reasons, EPA is proposing to approve the changes to this section. EPA's analysis of each rule change in Section .1400 included in the April 13, 2021, SIP revision is below.

a. Rule .1401, Definitions

Rule .1401 includes definitions that apply to Section .1400 rules. The April 13, 2021, SIP revision updates the formatting of rule references, makes minor clarifying changes, makes other formatting revisions and spelling/grammar corrections, adds definitions, and deletes one definition. Certain cross-references in Rule .1401 are changed to remove rules that North Carolina repealed (Rules .1416, .1417, and .1419 through .1422). These removed rules are also not in the SIP. Other revisions to Rule .1401 include:

1. A definition for "Combustion turbine" is added at .1401(a)(8). Stationary combustion turbines are regulated in Section 1400 under Rule .1408, and this definition provides clarity regarding that rule.
2. The definitions for "Emergency generator" at .1401(a)(11) and "Emergency use internal combustion engines" at .1401(a)(12) are each split into provisions (A) and (B) to make the definitions clearer. The revision also clarifies under (B) when the operation of emergency generators and emergency use internal combustion engines is allowed to perform maintenance to protect the environment. Currently, the SIP provision allows operation of such emergency generators and engines during maintenance when necessary to protect the environment. The revision specifies that operation for maintenance is only allowed when maintenance is performed on the power supply to equipment that is necessary to protect the environment and on such equipment itself.

3. The definition for "Process heater" at .1401(a)(20) is removed, as it is redundant with the definition for "Indirect-fired process heater" at

.1401(a)(15). Additionally, "indirect-fired process heater" is the term used in the substantive requirements of Section .1400 at .1407.

4. New provision .1401(b) is added to provide that whenever reference is made to the Code of Federal Regulations in Section .1400, the definitions in the Code of Federal Regulations shall apply unless specifically stated otherwise in a particular rule in this Section.

EPA is proposing to approve the April 13, 2021, SIP revision with respect to Rule .1401 because, as minor changes, they will not impact air quality and thus will not interfere with any requirement concerning attainment and reasonable progress, or any other applicable CAA requirement.⁴

b. Rule .1402, Applicability

Rule .1402 outlines the applicability provisions that apply to Section .1400 rules. The April 13, 2021, SIP revision does not include any substantive changes to Rule .1402. The revision makes minor administrative changes, makes minor rewording for clarity, removes outdated language referencing repealed rules, replaces words with acronyms for consistency, updates rule cross references, and updates the formatting of rule references. The cross-references in Rule .1402 are being changed to remove rules that North Carolina repealed (Rules .1416, .1417, and .1419 through .1422). A sentence in paragraph (a) was removed due to a reference to the Section .2400 rules related to the Clean Air Interstate Rule (CAIR), which North Carolina repealed. These removed rules are also not in the SIP.

EPA is proposing to approve the April 13, 2021, SIP revision with respect to Rule .1402 because, as minor, non-substantive changes, they will not impact air quality and thus will not interfere with any requirement concerning attainment and reasonable progress, or any other applicable CAA requirements.

c. Rule .1403, Compliance Schedules

Rule .1403 outlines compliance schedule provisions that apply to Section .1400 rules. The April 13, 2021, SIP revision does not include any substantive changes to Rule .1403. The revision updates the formatting of rule references, corrects an error in a rule reference in Subparagraph (b), and makes other general formatting and

minor administrative and clarifying changes.

EPA is proposing to approve the April 13, 2021, SIP revision with respect to Rule .1403 because, as minor, non-substantive changes, they will not impact air quality and thus will not interfere with any requirement concerning attainment and reasonable progress, or any other applicable CAA requirements.

d. Rule .1404, Recordkeeping: Reporting: Monitoring

Rule .1404 outlines recordkeeping, reporting, and monitoring provisions that apply to Section .1400 rules. Subparagraph (e)(2)(B) addresses "missing data" for continuous emissions monitoring systems and has been restructured to move the definition of "properly operated" to the end of the subparagraph. Additionally, the provision is strengthened by specifying that "properly operated" means that "operating and maintenance procedures being used complied with permit conditions, operating and maintenance procedures, preventative maintenance procedures, monitoring results, and compliance history," rather than only listing those specific procedures as examples of acceptable operating and maintenance procedures. Otherwise, the April 13, 2021, SIP revision does not include any substantive changes to Rule .1404 but includes updates to the formatting of rule references and minor administrative changes.

EPA is proposing to approve the April 13, 2021, SIP revision with respect to Rule .1404 because, as minor changes, they will not impact air quality and thus will not interfere with any requirement concerning attainment and reasonable progress, or any other applicable CAA requirements.

e. Rule .1407, Boilers and Indirect-Fired Process Heaters

Rule .1407 outlines provisions for boilers and indirect-fired process heaters. The April 13, 2021, SIP revision does not include any substantive changes to Rule .1407. The revision updates the formatting of rule references and abbreviations, and makes minor clarifications.

EPA is proposing to approve the April 13, 2021, SIP revision with respect to Rule .1407 because, as minor, non-substantive changes, they will not impact air quality and thus will not interfere with any requirement concerning attainment and reasonable progress, or any other applicable CAA requirements.

³ EPA is not proposing to act on Rule .1405, *Circumvention*, as this rule is not part of the approved SIP, and North Carolina did not request that EPA act on this rule.

⁴ Section 110(l) of the CAA prohibits EPA from approving a SIP revision that would interfere with any applicable requirement concerning attainment and reasonable further progress (as defined in section 171), or any other applicable requirement of the Act.

f. Rule .1408, Stationary Combustion Turbines

Rule .1408 outlines provisions for stationary combustion turbines. The April 13, 2021, SIP revision does not include any substantive changes to Rule .1408. The revision updates the formatting of rule references and abbreviations, and makes minor clarifications.

EPA is proposing to approve the April 13, 2021, SIP revision with respect to Rule .1408 because, as minor, non-substantive changes, they will not impact air quality and thus will not interfere with any requirement concerning attainment and reasonable progress, or any other applicable CAA requirements.

g. Rule .1409, Stationary Internal Combustion Engines

Rule .1409 outlines provisions for stationary internal combustion engines. The April 13, 2021, SIP revision does not include any substantive changes to Rule .1409. The revision corrects a cross-reference in Subparagraph (c), updates the formatting of rule references, updates abbreviations, adds “or she” to language referencing the Director, and makes minor administrative changes.

EPA is proposing to approve the April 13, 2021, SIP revision with respect to Rule .1409 because, as minor, non-substantive changes, they will not impact air quality and thus will not interfere with any requirement concerning attainment and reasonable progress, or any other applicable CAA requirements.

h. Rule .1410, Emissions Averaging

Rule .1410 outlines emissions averaging provisions that apply to Section .1400 rules. The April 13, 2021, SIP revision does not include any substantive changes to Rule .1410. The revision updates the formatting of rule references, updates abbreviations, and makes minor administrative changes.

EPA is proposing to approve the April 13, 2021, SIP revision with respect to Rule .1410 because, as minor, non-substantive changes, they will not impact air quality and thus will not interfere with any requirement concerning attainment and reasonable progress, or any other applicable CAA requirements.

i. Rule .1411, Seasonal Fuel Switching

Rule .1411 outlines provisions for seasonal fuel switching that apply to Section .1400 rules. The April 13, 2021, SIP revision does not include any substantive changes to Rule .1411. The revision updates the formatting of rule

references, updates abbreviations, and makes minor clarifying and administrative changes.

EPA is proposing to approve the April 13, 2021, SIP revision with respect to Rule .1411 because, as minor, non-substantive changes, they will not impact air quality and thus will not interfere with any requirement concerning attainment and reasonable progress, or any other applicable CAA requirements.

j. Rule .1412, Petition for Alternative Limitations

Rule .1412 outlines provisions to petition for alternative limitations. The April 13, 2021, SIP revision does not include any substantive changes to Rule .1412. The revision restructures Subparagraph (a), updates the formatting of rule references, adds “or she” to language referencing the Director, updates abbreviations, and makes minor administrative changes.

EPA is proposing to approve the April 13, 2021, SIP revision with respect to Rule .1412 because, as minor, non-substantive changes, they will not impact air quality and thus will not interfere with any requirement concerning attainment and reasonable progress, or any other applicable CAA requirements.

k. Rule .1413, Sources Not Otherwise Listed in This Section

Rule .1413 outlines provisions for sources not otherwise listed in Section .1400 rules. The April 13, 2021, SIP revision does not include any substantive changes to Rule .1413. The revision updates the formatting of rule references, adds “or she” to language referencing the Director, updates abbreviations, and makes minor administrative changes.

EPA is proposing to approve the April 13, 2021, SIP revision with respect to Rule .1413 because, as minor, non-substantive changes, they will not impact air quality and thus will not interfere with any requirement concerning attainment and reasonable progress, or any other applicable CAA requirements.

l. Rule .1414, Tune-Up Requirements

Rule .1414 outlines tune-up requirement provisions that apply to boilers, indirect-fired process heaters, and stationary internal combustion engines subject to Rule .1407 or .1409. The April 13, 2021, SIP revision does not include any substantive changes to Rule .1414. The revision updates the formatting of rule references, updates abbreviations, and makes minor clarifying and administrative changes.

EPA is proposing to approve the April 13, 2021, SIP revision with respect to Rule .1414 because, as minor, non-substantive changes, they will not impact air quality and thus will not interfere with any requirement concerning attainment and reasonable progress, or any other applicable CAA requirements.

m. Rule .1415, Test Methods and Procedures

Rule .1415 outlines provisions for test methods and procedures that apply to Section .1400 rules. The April 13, 2021, SIP revision does not include any substantive changes to Rule .1415. The revision updates the formatting of rule references.

EPA is proposing to approve the April 13, 2021, SIP revision with respect to Rule .1415 because, as minor, non-substantive changes, they will not impact air quality and thus will not interfere with any requirement concerning attainment and reasonable progress, or any other applicable CAA requirements.

n. Rule .1418, New Electric Generating Units, Boilers, Combustion Turbines, and I/C Engines

Rule .1418 outlines provisions for new electric generating units, boilers, combustion turbines, and internal combustion engines. The April 13, 2021, SIP revision does not include any substantive changes to Rule .1418. The revision updates the formatting of rule references, updates abbreviations, corrects errors in the rules title, restructures the provisions, and makes minor administrative changes.

EPA is proposing to approve the April 13, 2021, SIP revision with respect to Rule .1418 because, as minor, non-substantive changes, they will not impact air quality and thus will not interfere with any requirement concerning attainment and reasonable progress, or any other applicable CAA requirements.

o. Rule .1423, Large Internal Combustion Engines

Rule .1423 outlines provisions for large internal combustion engines. The April 13, 2021, SIP revision does not include any substantive changes to Rule .1423. The revision updates the formatting of rule references, updates abbreviations, and makes minor clarifying and administrative changes.

EPA is proposing to approve the April 13, 2021, SIP revision with respect to Rule .1423 because, as minor, non-substantive changes, they will not impact air quality and thus will not interfere with any requirement

concerning attainment and reasonable progress, or any other applicable CAA requirements.

III. Incorporation by Reference

In this document, EPA is proposing to include in a final EPA rule regulatory text that includes incorporation by reference. In accordance with the requirements of 1 CFR 51.5, EPA is proposing to incorporate by reference 15A NCAC Subchapter 02D .1401, *Definitions*; .1402, *Applicability*; .1403, *Compliance Schedules*; .1404 *Recordkeeping: Reporting: Monitoring*; .1407, *Boilers and Indirect-Fired Process Heaters*; .1408, *Stationary Combustion Turbines*; .1409, *Stationary Internal Combustion Engines*; .1410, *Emissions Averaging*; .1411, *Seasonal Fuel Switching*; .1412, *Petition for Alternative Limitations*; .1413, *Sources Not Otherwise Listed in this Section*; .1414, *Tune-Up Requirements*; .1415, *Test Methods and Procedures*; .1418, *New Electric Generating Units, Boilers, Combustion Turbines, And I/C Engines*; and .1423, *Large Internal Combustion Engines* as described in sections I and II of this preamble. These regulations were state-effective on October 1, 2020. EPA has made, and will continue to make, these materials generally available through www.regulations.gov and at the EPA Region 4 office (please contact the person identified in the **FOR FURTHER INFORMATION CONTACT** section of this preamble for more information).

IV. Proposed Action

EPA is proposing to approve the April 13, 2021, SIP revision to incorporate various changes to North Carolina's NO_x provisions into the SIP. Specifically, EPA is proposing to approve various minor changes to North

Carolina's rules in 02D Section .1400, *Nitrogen Oxides* as explained herein. EPA is proposing to approve these changes for the reasons discussed above.

V. Statutory and Executive Order Reviews

Under the CAA, the Administrator is required to approve a SIP submission that complies with the provisions of the Act and applicable Federal regulations. See 42 U.S.C. 7410(k); 40 CFR 52.02(a). Thus, in reviewing SIP submissions, EPA's role is to approve state choices, provided they meet the criteria of the CAA. This proposed action merely proposes to approve state law as meeting Federal requirements and does not impose additional requirements beyond those imposed by state law. For that reason, this proposed action:

- Is not a significant regulatory action subject to review by the Office of Management and Budget under Executive Orders 12866 (58 FR 51735, October 4, 1993) and 13563 (76 FR 3821, January 21, 2011);
- Does not impose an information collection burden under the provisions of the Paperwork Reduction Act (44 U.S.C. 3501 *et seq.*);
- Is certified as not having a significant economic impact on a substantial number of small entities under the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*);
- Does not contain any unfunded mandate or significantly or uniquely affect small governments, as described in the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4);
- Does not have Federalism implications as specified in Executive Order 13132 (64 FR 43255, August 10, 1999);
- Is not an economically significant regulatory action based on health or

safety risks subject to Executive Order 13045 (62 FR 19885, April 23, 1997);

- Is not a significant regulatory action subject to Executive Order 13211 (66 FR 28355, May 22, 2001);
- Is not subject to requirements of Section 12(d) of the National Technology Transfer and Advancement Act of 1995 (15 U.S.C. 272 note) because application of those requirements would be inconsistent with the CAA; and
- Does not provide EPA with the discretionary authority to address, as appropriate, disproportionate human health or environmental effects, using practicable and legally permissible methods, under Executive Order 12898 (59 FR 7629, February 16, 1994).

The SIP is not approved to apply on any Indian reservation land or in any other area where EPA or an Indian tribe has demonstrated that a tribe has jurisdiction. In those areas of Indian country, the rule does not have tribal implications as specified by Executive Order 13175 (65 FR 67249, November 9, 2000), nor will it impose substantial direct costs on tribal governments or preempt tribal law.

List of Subjects in 40 CFR Part 52

Environmental protection, Air pollution control, Carbon monoxide, Incorporation by reference, Intergovernmental relations, Lead, Nitrogen dioxide, Ozone, Particulate matter, Sulfur oxides, Volatile organic compounds.

Authority: 42 U.S.C. 7401 *et seq.*

Dated: November 15, 2022.

Daniel Blackman,

Regional Administrator, Region 4.

[FR Doc. 2022–25285 Filed 11–21–22; 8:45 am]

BILLING CODE 6560–50–P

Notices

Federal Register

Vol. 87, No. 224

Tuesday, November 22, 2022

This section of the FEDERAL REGISTER contains documents other than rules or proposed rules that are applicable to the public. Notices of hearings and investigations, committee meetings, agency decisions and rulings, delegations of authority, filing of petitions and applications and agency statements of organization and functions are examples of documents appearing in this section.

AGENCY FOR INTERNATIONAL DEVELOPMENT

Notice of Advisory Committee Public Meeting

AGENCY: Agency for International Development (USAID).

ACTION: Notice of Advisory Committee public meeting and request for public comment.

SUMMARY: Pursuant to the Federal Advisory Committee Act (FACA), notice is hereby given of Advisory Committee on Voluntary Foreign Aid (ACVFA) public meeting on Friday December 2, 2022.

ADDRESSES: To view additional information related to ACVFA please visit <http://www.usaid.gov/who-we-are/organization/advisory-committee>.

You may submit comments regarding the work of ACVFA to acvfa@usaid.gov OR the committee's public comment form at: <https://www.usaid.gov/who-we-are/organization/advisory-committee/acvfa-contact-us>. Include "Public Comment, ACVFA Meeting, December 2" in the subject line. All public comments and questions will be included in the official record of the meeting and posted publicly on the USAID website.

If you require a reasonable accommodation, please email reasonableaccommodations@usaid.gov. Include "Request for Reasonable Accommodation, ACVFA Meeting, December 2" in the subject line.

You may register to watch the live public meeting at this link: https://usaid.zoomgov.com/webinar/register/WN_oJoCBxYQ6y-1lb0z-BsFw.

FOR FURTHER INFORMATION CONTACT: Sophia Lajaunie, Designated Federal Officer for ACVFA, at slajaunie@usaid.gov or 917-804-3674.

SUPPLEMENTARY INFORMATION: ACVFA is USAID's external advisory committee, bringing together representatives from

private voluntary organizations, nongovernmental organizations (NGOs), academia, advocacy, and the private sector. Its membership of internationally recognized leaders represent a broad range of sectors who support the Agency's mission and goals by advising on key development challenges and priorities.

ACVFA was re-established earlier this year and pursuant to its charter, is holding an annual public meeting on December 2, 2022, from 10:15 a.m.–11:45 a.m. ET. This meeting is free and open to the public. The Committee welcomes public participation and comment before, during, and after the meeting via the web and/or email addresses provided above.

American Sign Language interpretation will be provided during the public meeting. If you require a reasonable accommodation, please email reasonableaccommodations@usaid.gov. Include "Request for Reasonable Accommodation, ACVFA Meeting, December 2" in the subject line.

Due to technical reasons, AID is providing notice announcing this meeting with less than a 15-day notice.

Sophia Lajaunie,

ACVFA Designated Federal Officer.

[FR Doc. 2022-25326 Filed 11-21-22; 8:45 am]

BILLING CODE 6116-01-P

DEPARTMENT OF AGRICULTURE

Submission for OMB Review; Comment Request

The Department of Agriculture will submit the following information collection requirement(s) to OMB for review and clearance under the Paperwork Reduction Act of 1995, Public Law 104-13 on or after the date of publication of this notice. Comments are requested regarding: whether the collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility; the accuracy of the agency's estimate of burden including the validity of the methodology and assumptions used; ways to enhance the quality, utility and clarity of the information to be collected; and ways to minimize the burden of the collection of information on those who are to

respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology Comments regarding these information collections are best assured of having their full effect if received by December 22, 2022. Written comments and recommendations for the proposed information collection should be submitted within 30 days of the publication of this notice on the following website www.reginfo.gov/public/do/PRAMain. Find this particular information collection by selecting "Currently under 30-day Review—Open for Public Comments" or by using the search function.

An agency may not conduct or sponsor a collection of information unless the collection of information displays a currently valid OMB control number and the agency informs potential persons who are to respond to the collection of information that such persons are not required to respond to the collection of information unless it displays a currently valid OMB control number.

Agricultural Marketing Service

Title: Almonds Grown in California (7 CFR part 981).

OMB Control Number: 0581-0242.

Summary of Collection: Marketing Order No. 981 (7 CFR part 981) regulates the handling of almonds grown in California and emanates from the Agricultural Marketing Agreement Act of 1937, (Act) Secs. 1-19, 48 Stat. 31, as amended (7 U.S.C. 601-674) to provide the respondents the type of service they request, and to administer the California almond marketing order program. The board has developed forms as a means for persons to file required information with the board relating to the treatment of almonds to reduce the potential for Salmonella bacteria prior to shipment.

Need and Use of the Information: The information collected is used only by authorized representatives of USDA, including AMS, Specialty Crops Program's regional and headquarters' staff, and authorized employees and agents of the Board. Authorized Board employees, agents, and the industry are the primary users of the information, and AMS is the secondary user.

Description of Respondents: Business or other for-profit.

Number of Respondents: 175.

Frequency of Responses:
Recordkeeping; Reporting: Annually;
On occasion.

Total Burden Hours: 4,200.

Levi S. Harrell,

*Departmental Information Collection
Clearance Officer.*

[FR Doc. 2022-25414 Filed 11-21-22; 8:45 am]

BILLING CODE 3410-18-P

DEPARTMENT OF AGRICULTURE

Food Safety and Inspection Service

[Docket No. FSIS-2022-0019]

Use of a Non-Destructive Surface Sampling Device To Sample Domestic Beef Manufacturing Trimmings and Bench Trim

AGENCY: Food Safety and Inspection Service (FSIS), U.S. Department of Agriculture (USDA).

ACTION: Notice and request for comments.

SUMMARY: On February 1, 2023, FSIS intends to stop using the N60 excision sampling method to sample domestic beef manufacturing trimmings and bench trim for adulterant Shiga toxin-producing *Escherichia coli* (*E. coli*) (STEC) and *Salmonella*. FSIS intends to replace the N60 excision sampling method with a non-destructive surface sampling method that uses a cloth manual sampling device. FSIS has found that the cloth sampling method is as effective as the N60 excision sampling method at recovering organisms in beef manufacturing trimmings. Additionally, the cloth sampling method is faster and safer for FSIS inspection program personnel (IPP) to use because it does not require IPP to use hooks or knives to collect samples. Moreover, the cloth sampling method allows FSIS to sample without destroying product, which reduces food waste.

DATES: FSIS will implement the cloth sampling on February 1, 2023, unless the Agency receives substantive comments that warrant further review. Submit comments on or before January 23, 2023.

ADDRESSES: FSIS invites interested persons to submit comments on this notice. Comments may be submitted by one of the following methods:

- *Federal eRulemaking Portal:* This website provides commenters the ability to type short comments directly into the comment field on the web page or to attach a file for lengthier comments. Go to <https://www.regulations.gov>. Follow

the on-line instructions at that site for submitting comments.

- *Mail:* Send to Docket Clerk, U.S. Department of Agriculture, Food Safety and Inspection Service, 1400 Independence Avenue SW, Mailstop 3758, Washington, DC 20250-3700.

- *Hand- or Courier-Delivered Submittals:* Deliver to 1400 Independence Avenue SW, Jamie L. Whitten Building, Room 350-E, DC 20250-3700.

Instructions: All items submitted by mail or electronic mail must include the Agency name and docket number FSIS-2022-0019. Comments received in response to this docket will be made available for public inspection and posted without change, including any personal information, to <https://www.regulations.gov>.

Docket: For access to background documents or comments received, call (202) 205-0495 to schedule a time to visit the FSIS Docket Room at 1400 Independence Avenue SW, Washington, DC 20250-3700.

FOR FURTHER INFORMATION CONTACT: Rachel Edelstein, Assistant Administrator, Office of Policy and Program Development by telephone at (202) 205-0495.

SUPPLEMENTARY INFORMATION:

Background

Under the Federal Meat Inspection Act (21 U.S.C. 601 *et seq.*), FSIS carries out an inspection program to ensure that carcasses, parts, and products of amenable species of livestock are wholesome, not adulterated, and properly marked, labeled, and packaged. FSIS conducts microbiological sampling to verify that establishments maintain control of their production processes and meet regulatory requirements, including requirements under the hazard analysis and critical control point (HACCP) regulations. Ongoing FSIS sampling and testing at official establishments allows FSIS to verify that establishments effectively address pathogens reasonably likely to occur in their products. The HACCP regulations (9 CFR part 417) require that establishments conduct a hazard analysis to determine the food safety hazards reasonably likely to occur in the production process and to identify the preventive measures an establishment can apply to control those hazards in the production of particular products.

Currently, FSIS samples and tests for *E. coli* O157:H7, non-O157 STEC (O26, O45, O103, O111, O121, or O145), and *Salmonella* in raw beef manufacturing trimmings and *E. coli* O157:H7 and *Salmonella* in bench trim verification

samples using the N60 excision sampling method, as described in FSIS Directive 10,010.1, Sampling Verification Activities for Shiga Toxin-Producing *Escherichia coli* (STEC) in Raw Beef Products.¹ The N60 excision sampling method is a destructive sampling method that requires inspection personnel to use knives or hooks to cut and collect at least 60 thin slices (approximately 3 inches long by 1 inch wide and 1/8 inch thick) from the external surface of beef tissues in a product lot.² The 60 samples are combined into one or more 325-gram units for analytical testing.

In recent years, FSIS and other agencies have been researching different methods for collecting samples from beef manufacturing trimmings that are less destructive and safer for inspectors to collect, yet still produce comparable results to the N60 excision sampling method.³ Findings from these studies provide strong scientific support for the use of cloth-based sampling for verification testing. Below is a discussion of the findings from different studies.

Agricultural Research Service (ARS) Sampling Studies

In 2018, USDA's ARS performed studies comparing the N60 excision sampling method and the N60 Plus⁴ to the cloth sampling method using a continuous sampling device and a manual sampling device.⁵ The continuous sampling device used a cloth held by a cassette attached to a bracket at the end of a conveyor line to collect samples as the meat rubbed across the cloth⁶ and fell into the combo bins. The manual sampling device used the same type of cloth as the continuous sampling device, and it was used to manually rub all trim across the entire top surface of the combo bin to collect a sample. The manual sampling device

¹ <https://www.fsis.usda.gov/policy/fsis-directives/10010.1>.

² Establishments determine their lot size. A lot is usually made up of no more than five, 2,000-pound combo bins of beef trimmings or less than 10,000 pounds if the establishment is using boxes.

³ See 85 FR 34397 and FSIS' *Constituent Update—December 18, 2020* (Food Safety and Inspection Service ([usda.gov](https://www.fsis.usda.gov))), which is available at: <https://www.fsis.usda.gov/news-events/news-press-releases/constituent-update-december-18-2020>.

⁴ N60 Plus is similar to the N60 excision sampling method, but it uses a stainless-steel sampling device on a drill to collect surface tissue.

⁵ Wheeler, T.L. & Arthur T.M. (2018). Novel Continuous and Manual Sampling Methods for Beef Trim Microbiological Testing. *Journal of Food Protection*, 81(10), 1605-1613. <https://doi.org/10.4315/0362-028X.JFP-18-197>.

⁶ ARS initially used the continuous sampling device with a cellulose sponge. However, ARS quickly determined that the cellulose sponge was too expensive for commercial implementation.

was found to be best for hand-picked and other bin-fill stations where the continuous sampling device could not be installed. ARS conducted experiments testing for naturally occurring *E. coli* O157:H7 and *Salmonella*, inoculated surrogates (green fluorescent protein-labeled (GFP) *E. coli*), and indicator organisms (aerobic plate count (APC), generic *E. coli*, and coliforms) in five different processing establishments, on multiple days, across multiple lean percentages (50, 80, 90, and 93 percent lean). Experiments with natural contamination (substances already in the environment) found no *E. coli* O157:H7, no statistically significant difference in prevalence of *Salmonella* (continuous sampling device 9.2 percent versus N60 excision sampling device 6.0 percent) and similar levels of indicator organisms for the continuous sampling device compared with both the N60 excision and N60 Plus sampling methods. In additional experiments, the continuous sampling device found the same or higher prevalence of naturally occurring *E. coli* O157:H7 and GFP *E. coli*, as well as similar levels of indicator organisms compared with the N60 method. In the next experiment, the manual sampling device found similar prevalence of *E. coli* O157:H7 surrogate organisms, and slightly lower ($P < 0.05$) levels of indicator organisms compared with N60 Plus. An additional experiment showed the manual sampling device found similar prevalence of naturally occurring *E. coli* O157:H7 and the same or slightly higher ($P < 0.05$) levels of naturally occurring indicator organisms compared with N60 Plus. In a further experiment, the manual sampling device detected the same prevalence of naturally occurring *Salmonella* as the N60 excision sampling method. ARS concluded that the results of their experiments collectively demonstrated that sampling beef trim using the cloth sampling method (using either a continuous sampling device or manual sampling device) provides organism recovery that is similar, comparable to or better than the N60 excision sampling method.

In 2021, ARS conducted another study to determine the efficacy of the cloth sampling method in scenarios that included smaller combo bins.⁷ ARS collected 1,650 matched (cloth and N60) samples collected at the same time from 540 individual combo bins at six

commercial beef processing establishments, comparing the cloth sampling method (using both continuous and manual sampling devices) to the N60 excision sampling method and N60 Plus. In this second study, ARS analyzed the presence of select virulence associated genes (hemolysin, five non-adherent O serogroups (O55, O113, O117, O126, and O146), intimin, heme receptor, adhesion siderophore, *tetA* and *tetB*) to act as index targets—measures that would correlate with the percent positive of STEC and *Salmonella*. One experiment observed no difference in the percent positive for pathogen index targets from product at two lean types, between the cloth manual sampling device and N60 excision method ($n=185$). When evaluated on combo bins with a smaller surface area ($\approx 0.93 \text{ m}^2$ [ca. 1,439 in²] instead of 1 m^2 [ca. 1,600 in²]), the manual sampling device had a higher percent positive for the heme receptor gene target (52.5 versus 25 percent) and recovered 0.3 log₁₀ more aerobic bacteria (APC) than the N60 Plus method ($P < 0.05$; $n=40$).

In a further experiment on smaller surface area combo bins, the cloth manual sampling device method recovered more O serogroup positive samples than the N60 Plus (86.3 percent and 63.8 percent respectively; $P < 0.05$). The cloth manual sampling device also recovered 0.2 log₁₀ more *Enterobacteriaceae* than N60 Plus ($n=80$). There was no difference between the cloth manual sampling device and N60 Plus recovery of five other pathogen index target genes and aerobic plate count (APC).

In one final experiment, 80 combo bins were sampled to compare the continuous sampling device, manual sampling device, and N60 Plus methods. There were no significant differences among the three sample collection methods for any of the pathogen index gene targets. As a result, ARS concluded that their study supports various alternative applications of the cloth sampling method for robust pathogen detection. Based on ARS' research, FSIS issued a letter of no objection in March 2017 to allow industry to use cloth sampling methods for microbiological sampling of raw beef trim and a second letter of no objection in March 2020 for specific in-plant validation procedures.

FSIS In-Field Studies

Starting in December 2019, and still ongoing, FSIS performed a combination of laboratory and field studies to compare the N60 excision sampling method to the cloth sampling method.

The project began with an initial laboratory study to compare *Salmonella* and STEC recovery using polyurethane sponge and cloth sampling methods against the current N60 excision sampling method. The laboratory used raw beef trim reserves that previously tested negative for *Salmonella* and STEC to prepare samples simulating IPP collected product. FSIS laboratory microbiologists inoculated the beef trim with *E. coli* O157:H7, and non-O157 (O103 and O121)) and *Salmonella* at low levels (3.5–7.5 cfu/2—pound test bin). Microbiologists used a dry cloth to sample and simulate the shipment of samples. After reviewing analyte recovery of each technique, the cloth sampling method was selected for additional review in the field because there was no difference in *E. coli* O157:H7 or O103 recovery. Although the cloth recovered significantly less O121, there was no difference in *Salmonella* recovery. Overall, the cloth sampling method recovered pathogens when present in the product sampled that had been inoculated at very low levels.

FSIS then conducted an exploratory field study to directly compare the manual cloth sampling method as developed by ARS, to the N60 excision sampling method when performing inspection verification of establishment beef trim. IPP collected the beef trim samples in the exploratory study matched with routine N60 samples and analyzed both for APC and *Salmonella*. Based on preliminary results, FSIS considered if the cloth manual sampling method may be improved by addition of a neutralizing buffer before shipping.

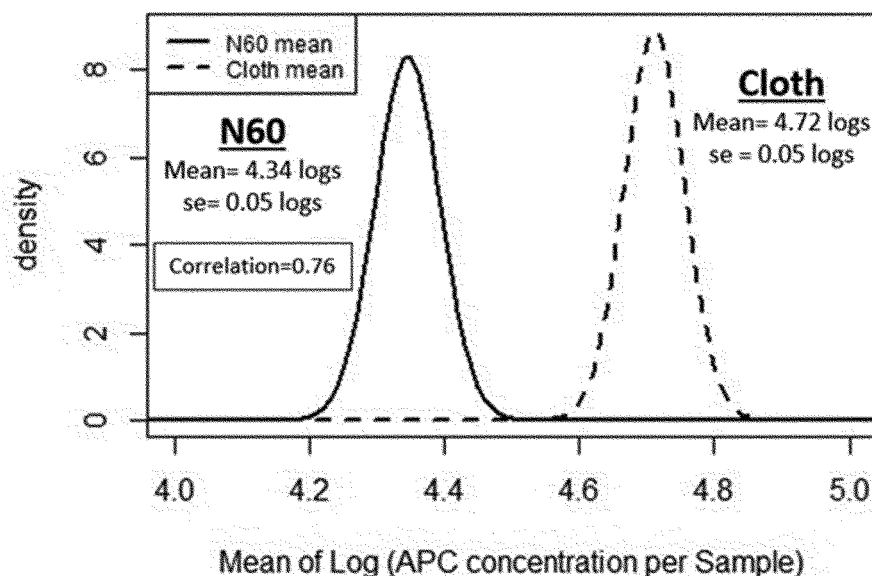
The second laboratory study evaluated neutralizing buffer options for the cloth sampling method. FSIS laboratory microbiologists inoculated beef trim with *E. coli* O157:H7 at concentrations of 5–10 cfu/cloth and *Salmonella* $\sim 5 \times 10^4$ cfu/cloth. FSIS tested three treatments: (1) 25 mL neutralizing Buffered Peptone Water (nBPW) (2), 25mL buffered peptone water (BPW), and (3) a dry cloth. Adding the transport buffer nBPW to the cloth after inoculation and before simulated shipping improved analyte recovery by 0.16 log more than when the dry cloth (*i.e.*, no transport buffer) was used. Using nBPW did not inhibit screening or survival or recovery of *E. coli* O157:H7 compared with the dry cloth.

This led to a final field study where IPP began adding 25 mL of nBPW as a transport buffer to cloth samples after collection and before shipping to further protect sample integrity during transit. This study showed that the cloth

⁷ Arthur T.M. & Wheeler T.L. (2021). Validation of Additional Approaches and Applications for Using the Continuous and Manual Sampling Devices for Raw Beef Trim. *Journal of Food Protection*, 84(4), 536–544. <https://doi.org/10.4315/JFP-20-345>.

sampling method plus the addition of the transport buffer recovered significantly more bacteria (0.38 log

Aerobic Count) than the N60 sampling method (see diagram below).⁸



FSIS also tested for *Salmonella*, based on the current data, the differences in results were not significantly different (N60 2.0 percent; cloth 1.7 percent).

FSIS conducted a qualitative review of noncompliance reports (NRs) for establishments failing to detect STEC when FSIS verification sampling detected a STEC positive sample result. FSIS used data from samples of beef manufacturing trimmings and bench trim collected between April 2015 and December 2021 to determine if establishments using the cloth sampling method failed to detect STEC when concurrent FSIS testing found a positive sample collected using N60. Some establishments began using the cloth sampling method in 2017, but industry more widely adopted cloth sampling after March 2020 when FSIS issued a second letter of no objection for in-plant validation procedures for cloth sampling. NRs, from a total of 15 establishments, citing 9 CFR 310.2 and 417.4(a) issued during three periods were reviewed: before cloth implementation (8 NRs), during the transition period (11 NRs), and after establishments began cloth sampling (4 NRs). The analysis showed that industry adopting cloth sampling did not increase NRs due to missed STEC positive lots. Most of the NRs that were

issued after cloth implementation were due to the establishments only testing for *E. coli* O157:H7 and failing to detect non-O157 adulterant STEC-positive product. Careful consideration of these various studies⁹ have led FSIS to conclude that there is no significant difference in microbial recovery between cloth manual sampling and N60 excision methods. FSIS has determined the cloth sampling method with nBPW is equivalent to N60 excision sampling.

FSIS Implementation Plan

FSIS will replace the N60 excision sampling of domestic beef manufacturing trimmings and bench trim with the cloth sampling method, including nBPW transport buffer. At this time, FSIS does not intend to implement any changes to the sample collection method for frozen imported products or any domestic raw beef processed products other than beef manufacturing trimmings and bench trim using the cloth sampling method. No one has evaluated the cloth's ability to recover bacteria from frozen beef products. USDA ARS researchers recommend against sampling frozen beef trim with the cloth since there is no liquid for the cloth to absorb and collect. Also, FSIS will continue to use

the current directions in FSIS Directive 10,010.1, Sampling Verification Activities for Shiga Toxin Producing *Escherichia coli* (STEC) in Raw Beef Products¹⁰ for sampling ground beef and other raw ground beef components including head meat, cheek meat, weasand (esophagus) meat, product from advanced meat recovery (AMR) systems, partially defatted chopped beef and partially defatted beef fatty tissue, low temperature rendered lean finely textured beef, and heart meat.

Costs and Benefits Analysis

The Agency does not expect the implementation of cloth sampling for the sampling of beef manufacturing trimmings and bench trim by FSIS to have a cost impact on the industry. As described before, both ARS studies and FSIS in-field studies have found no statistically significant change in testing results.

The change will enable FSIS to allocate some resources, including supplies, shipping costs, and analysis time, to other sampling verification activities. It may also reduce inspector injuries as they will no longer be using knives to sample product, as well as decrease sample collection time. Finally, the non-destructive sampling will also save food (meat) from being cut

⁸ The units on the y-axis are probability densities that are calculated for normal distributions with mean and standard error (se) values as shown. Probability density—or density—can be interpreted as relative likelihood of the x-axis values.

⁹ Scientific Support for FSIS to Use a Surface Sampling Method for Beef Trim PowerPoint available at: https://www.fsis.usda.gov/sites/default/files/media_file/documents/FSIS_N60vClothSampling-RawBeefTrim_20221107_v2.7B.ppt.

¹⁰ FSIS Directive 10,010.1 Revision 4—Sampling Verification Activities for Shiga Toxin-Producing *Escherichia coli* (STEC) in Raw Beef Products available at: https://www.fsis.usda.gov/sites/default/files/media_file/2020-07/10010.1.pdf.

and wasted, at about 2 pounds per sample.

Conclusion

Based on the above studies showing the effectiveness of cloth sampling in recovering indicator organisms and pathogens and the resources saved by FSIS, the Agency plans to move forward with using cloth sampling in lieu of N60 excision sampling on beef manufacturing trimmings and bench trim. FSIS also anticipates saving resources by adopting this change.

USDA Non-Discrimination Statement

In accordance with Federal civil rights law and U.S. Department of Agriculture (USDA) civil rights regulations and policies, USDA, its Mission Areas, agencies, staff offices, employees, and institutions participating in or administering USDA programs are prohibited from discriminating based on race, color, national origin, religion, sex, gender identity (including gender expression), sexual orientation, disability, age, marital status, family/parental status, income derived from a public assistance program, political beliefs, or reprisal or retaliation for prior civil rights activity, in any program or activity conducted or funded by USDA (not all bases apply to all programs). Remedies and complaint filing deadlines vary by program or incident.

Program information may be made available in languages other than English. Persons with disabilities who require alternative means of communication to obtain program information (e.g., Braille, large print, audiotope, American Sign Language) should contact the responsible Mission Area, agency, or staff office; the USDA TARGET Center at (202) 720-2600 (voice and TTY); or the Federal Relay Service at (800) 877-8339.

To file a program discrimination complaint, a complainant should complete a Form AD-3027, *USDA Program Discrimination Complaint Form*, which can be obtained online at <https://www.ocio.usda.gov/document/ad-3027>, from any USDA office, by calling (866) 632-9992, or by writing a letter addressed to USDA. The letter must contain the complainant's name, address, telephone number, and a written description of the alleged discriminatory action in sufficient detail to inform the Assistant Secretary for Civil Rights (ASCR) about the nature and date of an alleged civil rights violation. The completed AD-3027 form or letter must be submitted to USDA by:

(1) *Mail*: U.S. Department of Agriculture, Office of the Assistant

Secretary for Civil Rights, 1400 Independence Avenue SW, Washington, DC 20250-9410; or

(2) *Fax*: (833) 256-1665 or (202) 690-7442; or

(3) *Email*: program.intake@usda.gov
USDA is an equal opportunity provider, employer, and lender.

Additional Public Notification

Public awareness of all segments of rulemaking and policy development is important. Consequently, FSIS will announce this **Federal Register** publication on-line through the FSIS web page located at: <https://www.fsis.usda.gov/federal-register>.

FSIS will also announce and provide a link to it through the FSIS *Constituent Update*, which is used to provide information regarding FSIS policies, procedures, regulations, **Federal Register** notices, FSIS public meetings, and other types of information that could affect or would be of interest to our constituents and stakeholders. The *Constituent Update* is available on the FSIS web page. Through the web page, FSIS is able to provide information to a much broader, more diverse audience. In addition, FSIS offers an email subscription service which provides automatic and customized access to selected food safety news and information. This service is available at: <https://www.fsis.usda.gov/subscribe>. Options range from recalls to export information, regulations, directives, and notices. Customers can add or delete subscriptions themselves and have the option to password protect their accounts.

Done at Washington, DC.

Paul Kiecker,
Administrator.

[FR Doc. 2022-25333 Filed 11-21-22; 8:45 am]

BILLING CODE 3410-DM-P

DEPARTMENT OF AGRICULTURE

Food and Nutrition Service

Agency Information Collection Activities: Supplemental Nutrition Assistance Program Emergency Allotments (COVID-19)

AGENCY: Food and Nutrition Service (FNS), USDA.

ACTION: Notice.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995, this notice invites the general public and other public agencies to comment on this proposed information collection. This collection is an extension, without change, of a currently approved

collection for activities associated with administering emergency allotments (EA) waivers. The Families First Coronavirus Response Act of 2020, enacted March 18, 2020, includes a general provision that allows the Department of Agriculture to issue EA waivers based on a public health emergency declaration by the Secretary of Health and Human Services under section 319 of the Public Health Service Act related to an outbreak of COVID-19 when a State has also issued an emergency or disaster declaration.

DATES: Written comments must be received on or before January 23, 2023.

ADDRESSES: Comments may be sent to: Erica Kain, Food and Nutrition Service, U.S. Department of Agriculture, 1320 Braddock Place, 5th Floor, Alexandria, VA 22314; or by phone at (312) 339-1939. Comments may also be submitted via email to SM.FN.SNAP.Issuance.Policy@usda.gov. Comments will also be accepted through the Federal eRulemaking Portal. Go to <http://www.regulations.gov>, and follow the online instructions for submitting comments electronically.

All responses to this notice will be summarized and included in the request for Office of Management and Budget approval. All comments will be a matter of public record.

FOR FURTHER INFORMATION CONTACT: Requests for additional information or copies of this information collection should be directed to Erica Kain at SM.FN.SNAP.Issuance.Policy@usda.gov; or by phone at (312) 339-1939.

SUPPLEMENTARY INFORMATION: Comments are invited on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions that were used; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on those who are to respond, including use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology.

Title: Agency Information Collection Activities: Supplemental Nutrition Assistance Program Emergency Allotments (COVID-19).

OMB Number: 0584-0652.

Expiration Date: 8/31/2023.

Type of Request: Extension, without change, of a currently approved collection.

Abstract: The Families First Coronavirus Response Act of 2020 (Pub. L. 116–127), enacted March 18, 2020, includes a general provision that allows the Department of Agriculture to issue emergency allotments (EA) based on a public health emergency declaration by the Secretary of Health and Human Services under section 319 of the Public Health Service Act related to an outbreak of COVID–19 when a State has also issued an emergency or disaster declaration. In January 2021, the Department obtained Office of Management and Budget (OMB) approval to collect the information as described in this Notice for a period of one year (OMB Control Number 0584–0652; expiration 1/31/2022). The President’s *Executive Order on Economic Relief Related to the COVID–19 Pandemic*, issued January 22, 2021, directed all Federal agencies to consider administrative actions to better address the current economic crisis resulting from the pandemic. FNS reviewed existing EA policy and issued updated State guidance¹ on April 1, 2021, outlining a new approach to calculating EA that provides greater equity for households most in need. The April 2021 guidance superseded previous guidance issued in March 2020 and April 2020. In addition to outlining a new EA minimum benefit policy, the April 2021 guidance described an EA phase-out request States may use when their State-level emergency declaration expiration date is imminent. The State agency process for requesting EA, as outlined in the April 2021 guidance, now includes an attestation requirement confirming that the State’s emergency or disaster declaration remains active when requesting EA. On May 21, 2021, FNS provided further operational guidance to SNAP State Agencies and Regional Offices in a Q&A document provided in response to questions raised during webinars based on the April 1, 2021 guidance.² FNS reiterated April 1, 2021 guidance in a memorandum dated December 14, 2021, in which FNS described the EA phase-out process.³ USDA anticipates the need to collect the data beyond the expiration date and is seeking approval of this Information Collection Request in order to meet the

continuing information collection and reporting requirements detailed in the Families First Coronavirus Response Act of 2020.

As authorized by Families First Coronavirus Response Act of 2020, State agencies impacted by COVID–19 may submit an EA waiver request to their FNS Regional Office for approval to provide an EA to households to bring all households up to the maximum benefit due to pandemic related economic conditions. As outlined in the April 2021 guidance, State agency waivers will generally be approved under one or more the following conditions as it relates to COVID–19:

- Residents of the State are confirmed to have contracted COVID–19.
- Some or all areas of the State are containment or quarantine zones.
- Businesses have closed or significantly reduced their hours.
- The State’s residents have experienced economic impacts due to job suspensions or losses.
- The State’s residents have been directed to practice social distancing.

The State agency must also confirm that the State’s emergency or disaster declaration remains active.

In addition, to allow for State EA phase-out upon expiration of the State’s emergency declaration, States may request EA approval for one additional issuance month if:

- The national public health emergency declaration that was extended on October 13, 2022, by the Secretary for Health and Human Services under section 319 of the Public Health Service Act remains in place, and
- The State-issued emergency or disaster declaration has expired or will expire in the current month. This will allow a State that has lost or will lose its declaration in the current month to provide one additional issuance month of EA and to notify SNAP participants that EA benefits will be ending.

Once the State’s EA waiver has been approved by FNS, the State may provide the EA without contacting the household. Following waiver approval, FNS will require State Agencies to attest to FNS on a monthly basis the EA waiver is still needed and that the State declaration remains in place. Both the initial EA waiver and the monthly attestation are conducted via email. FNS expects 53 State agencies will submit one initial EA waiver to FNS. Currently 36 State agencies are operating under an EA waiver. Although there are currently less than 53 States operating under an EA waiver, it is possible that States may have more than one declared public health emergency over the next few

years as COVID–19 rates ebb and flow. For this reason, we are including hours for the entire universe for State agencies. We are requesting approval for 53 initial waiver requests in this IC as a precautionary measure.

There are three reporting requirements for this information collection request. (1) Each initial EA waiver submission should take approximately one hour to complete. (2) Each monthly email attesting to the continued need for the EA waiver is expected to take 15 minutes to complete. FNS expects that any phase-out request, as outlined in the April 2021 guidance, would be included in the email as part of the monthly attestation process; the indication of phase-out would simply signal the end of that State’s need for EA and, thus, monthly attestations. The phase out request is expected to take 1 minute of the 15 minutes estimated for monthly attestation; therefore, no additional burden is estimated for phase-out requests.

Section 18(b) of the Food and Nutrition Act of 2008, as amended, requires that, “In any fiscal year, the Secretary shall limit the value of those allotments issued to an amount not in excess of the appropriation for such fiscal year.” Because the EA waiver increases the monthly benefit of participants above the amount originally anticipated for this fiscal year, the amount of benefits issued and redeemed must be carefully tracked to ensure FNS does not exceed its appropriation. As such, it is necessary for FNS to collect information from State agencies operating EA on a more frequent basis than would be reported normally. Generally, States report disaster-related SNAP participation and issuance data to FNS on the FNS–292B, Report of Disaster Supplemental Nutrition Assistance Benefit Issuance, within 45 days of terminating disaster assistance.

While a State is operating under an EA waiver, (3) FNS requires the State to submit *bi-weekly* FNS–292B reports. The burden for a State agency to submit FNS–292B reports during normal operations is currently captured under the information collection for the Food Programs Reporting System (FPRS), OMB Control Number 0584–0594 (expiration date 7/31/2023). However, FNS is accounting for the additional burden used for EA in this request and including the burden for submitting this form more frequently under this information collection and is not duplicating the burden efforts for the routine normal operations captured in the FPRS collection.

¹ <https://fns-prod.azureedge.net/sites/default/files/resource-files/snap-covid-emergency-allotments-phase-3-guidance.pdf>.

² https://fns-prod.azureedge.us/sites/default/files/resource-files/EA%20QAs_5_20_2021_FINAL.pdf.

³ <https://fns-prod.azureedge.us/sites/default/files/resource-files/snap-ea-information-end-national-phe.pdf>.

• FNS–292B—Takes States approximately 24 minutes or 0.4008 hours per response × 53 State Agencies × 26 weeks = 552.30 hours.
Affected Public: State, Local and Tribal Governments.

Estimated Number of Respondents: 53.
Estimated Number of Responses per Respondent: 39.
Estimated Total Annual Responses: 2,067.

Estimated Time per Response: 0.36976294 hours.
Estimated Total Annual Burden on Respondents: 764.30.

Respondent category	Instruments	Form	Number of respondents	Frequency of response	Total annual responses	Hours per response	Annual burden (hours)
State Agencies ...	Bi-weekly EA Reporting to FNS	FNS–292B	53	26	1,378	0.4008	552.20
	Initial Waiver Request—Emergency Allotment.	N/A	53	1	53	1	53
	Monthly EA Attestation (including Phase-Out Requests).	N/A	53	12	636	0.25	159
Total	53	39	2,067	0.36976294	764.30

Tameka Owens,

Assistant Administrator, Food and Nutrition Service.

[FR Doc. 2022–25410 Filed 11–21–22; 8:45 am]

BILLING CODE 3410–30–P

COMMISSION ON CIVIL RIGHTS

Notice of Public Meeting of the Minnesota Advisory Committee to the U.S. Commission on Civil Rights

AGENCY: U.S. Commission on Civil Rights.

ACTION: Announcement of virtual business meeting.

SUMMARY: Notice is hereby given, pursuant to the provisions of the rules and regulations of the U.S. Commission on Civil Rights (Commission) and the Federal Advisory Committee Act, that the Minnesota Advisory Committee (Committee) to the U.S. Commission on Civil Rights will hold a virtual business meeting via Zoom at 1 p.m. CT on Monday, December 12, 2022, to discuss the next topic of study for the Committee.

DATES: The meeting will take place on Monday, December 12, 2022, from 1 p.m.–2 p.m. CT.

ADDRESSES:

Registration Link (Audio/Visual):
<https://tinyurl.com/ydpn2ar2>.

Telephone (Audio Only): Dial (833) 435–1820 USA Toll Free; Meeting ID: 161 885 1683.

FOR FURTHER INFORMATION CONTACT: David Barreras, DFO, at dbarreras@usccr.gov or (202) 656–8937.

SUPPLEMENTARY INFORMATION:

Committee meetings are available to the public through the videoconference link above. Any interested member of the public may listen to the meeting. An open comment period will be provided to allow members of the public to make a statement as time allows. Per the Federal Advisory Committee Act,

members of the public who wish to speak during public comment must provide their name to the Commission; however, if a member of the public wishes to join anonymously, we ask that you please join by phone. If joining via phone, callers can expect to incur regular charges for calls they initiate over wireless lines, according to their wireless plan. The Commission will not refund any incurred charges. Closed captions will be provided for individuals who are deaf, deafblind, or hard of hearing. To request additional accommodations, please email dbarreras@usccr.gov at least 10 business days prior to the meeting.

Members of the public are also entitled to submit written comments; the comments must be received in the regional office within 30 days following the meeting. Written comments may be emailed to Liliana Schiller at lschiller@usccr.gov. Persons who desire additional information may contact the Regional Programs Coordination Unit at (202) 809–9618.

Records generated from this meeting may be inspected and reproduced at the Regional Programs Coordination Unit, as they become available, both before and after the meeting. Records of the meeting will be available via www.facadatabase.gov under the Commission on Civil Rights, Minnesota Advisory Committee link. Persons interested in the work of this Committee are directed to the Commission's website, <http://www.usccr.gov>, or may contact the Regional Programs Coordination Unit at the above phone number.

Agenda

- I. Welcome & Roll Call
- II. Approval of Meeting Minutes
- III. Discussion: Civil Rights Concerns in Minnesota
- IV. Public Comment
- V. Next Steps
- VI. Adjournment

Dated: November 17, 2022.

David Mussatt,

Supervisory Chief, Regional Programs Unit.

[FR Doc. 2022–25424 Filed 11–21–22; 8:45 am]

BILLING CODE 6335–01–P

COMMISSION ON CIVIL RIGHTS

Notice of Public Meeting of the Guam Advisory Committee to the U.S. Commission on Civil Rights

AGENCY: U.S. Commission on Civil Rights.

ACTION: Announcement of virtual business meeting.

SUMMARY: Notice is hereby given, pursuant to the provisions of the rules and regulations of the U.S. Commission on Civil Rights (Commission) and the Federal Advisory Committee Act, that the Guam Advisory Committee (Committee) to the U.S. Commission on Civil Rights will hold a virtual business meeting via Zoom at 11 a.m. ChST on Tuesday, December 6, 2022, (8 p.m. ET on Monday, December 5, 2022) to continue discussing the Committee's project on housing discrimination.

DATES: The meeting will take place on Tuesday, December 6, 2022, from 11 a.m.–12:30 p.m. ChST (Monday, December 5, 2022, from 8 p.m.–9:30 p.m. ET).

ADDRESSES:

Registration Link (Audio/Visual):
<https://tinyurl.com/34srpuwj>.

Telephone (Audio Only): Dial (833) 435–1820 USA Toll Free; Meeting ID: 160 583 8340.

FOR FURTHER INFORMATION CONTACT:

Kayla Fajota, DFO, at kfajota@usccr.gov or (434) 515–2395.

SUPPLEMENTARY INFORMATION:

Committee meetings are available to the public through the videoconference link above. Any interested member of the public may listen to the meeting. An open comment period will be provided to allow members of the public to make

a statement as time allows. Per the Federal Advisory Committee Act, members of the public who wish to speak during public comment must provide their name to the Commission; however, if a member of the public wishes to join anonymously, we ask that you please join by phone. If joining via phone, callers can expect to incur regular charges for calls they initiate over wireless lines, according to their wireless plan. The Commission will not refund any incurred charges. Closed captions will be provided for individuals who are deaf, deafblind, or hard of hearing. To request additional accommodations, please email kfajota@usccr.gov at least 10 business days prior to the meeting.

Members of the public are also entitled to submit written comments; the comments must be received in the regional office within 30 days following the meeting. Written comments may be emailed to Liliana Schiller at lschiller@usccr.gov. Persons who desire additional information may contact the Regional Programs Coordination Unit at (202) 809-9618.

Records generated from this meeting may be inspected and reproduced at the Regional Programs Coordination Unit, as they become available, both before and after the meeting. Records of the meeting will be available via www.facadatabase.gov under the Commission on Civil Rights, Guam Advisory Committee link. Persons interested in the work of this Committee are directed to the Commission's website, <http://www.usccr.gov>, or may contact the Regional Programs Coordination Unit at the above phone number.

Agenda

- I. Welcome & Roll Call
- II. Announcements & Updates
- III. Approval of Meeting Minutes
- IV. Public Comment
- V. Discussion: Housing Discrimination
- VI. Next Steps
- VII. Adjournment

Dated: November 17, 2022.

David Mussatt,

Supervisory Chief, Regional Programs Unit.

[FR Doc. 2022-25423 Filed 11-21-22; 8:45 am]

BILLING CODE 6335-01-P

COMMISSION ON CIVIL RIGHTS

Notice of Public Meeting of the Connecticut Advisory Committee

AGENCY: Commission on Civil Rights.

ACTION: Announcement of meeting.

SUMMARY: Notice is hereby given, pursuant to the provisions of the rules

and regulations of the U.S. Commission on Civil Rights (Commission), and the Federal Advisory Committee Act (FACA), that the Connecticut Advisory Committee to the U.S. Commission on Civil Rights will hold a third briefing on the impact of algorithms on civil rights in Connecticut on Monday, December 19, 2022, at 2 p.m. (ET). The briefing will convene virtually. The purpose of the briefing is to hear from an expert on the topic of algorithms and civil rights in Connecticut. The committee will also hold a planning meeting after the briefing.

DATE AND TIME: Monday, December 19, 2022; 2 p.m. (ET).

Zoom Link (audio/video): <https://tinyurl.com/2p886878>; passcode, if needed: USCCR-CT.

If Joining by Phone Only: 1-551-285-1373; Meeting ID: 161 410 6352#.

FOR FURTHER INFORMATION CONTACT: Barbara Delaviez at ero@usccr.gov or by phone at 202-539-8246.

SUPPLEMENTARY INFORMATION: If other persons who plan to attend the meeting require other accommodations, please contact Evelyn Bohor at ebohor@usccr.gov at the Eastern Regional Office at least ten (10) working days before the scheduled date of the meeting. During the meeting, closed captioning will be available to you as needed.

Members of the public are entitled to make comments during the open comment period towards the end of the meeting. Members of the public may also submit written comments; the comments must be received in the Regional Programs Unit within 30 days following the meeting. Written comments may be emailed to Barbara de La Viez at ero@usccr.gov. Persons who desire additional information may contact the Regional Programs Unit at (202) 539-8246. Records and documents discussed during the meeting will be available for public viewing as they become available at www.facadatabase.gov. Persons interested in the work of this advisory committee are advised to go to the Commission's website, www.usccr.gov, or to contact the Regional Programs Unit at the above phone number or email address.

Agenda

Monday, December 19, 2022; 2 p.m. (ET)

- I. Welcome and Roll Call
- II. Briefing Panel IV: The Impact of Algorithms on Civil Rights in Connecticut
- III. Question and Answer Between Panelist and Committee Members
- IV. Public Comment
- V. Briefing Planning

VI. Adjournment

Dated: November 17, 2022.

David Mussatt,

Supervisory Chief, Regional Programs Unit.

[FR Doc. 2022-25422 Filed 11-21-22; 8:45 am]

BILLING CODE 6335-01-P

COMMISSION ON CIVIL RIGHTS

Notice of Public Meeting of the Puerto Rico Advisory Committee

AGENCY: Commission on Civil Rights.

ACTION: Announcement of meeting.

SUMMARY: Notice is hereby given, pursuant to the provisions of the rules and regulations of the U.S. Commission on Civil Rights (Commission), and the Federal Advisory Committee Act (FACA), that a meeting of the Puerto Rico Advisory Committee to the Commission will convene by virtual web conference on Wednesday, December 14, 2022, at 1:00 p.m. (AT). The purpose is to discuss their project proposal on the civil rights impacts of the Insular Cases in Puerto Rico.

DATES: December 14, 2022, Wednesday, at 1 p.m. (AT).

ADDRESSES:

- To join by web conference, use Zoom link: <https://tinyurl.com/hhntssxd>; password, if needed: USCCR-PR
- To join by phone only, dial 1-551-285-1373; Meeting ID: 160 333 3735#

FOR FURTHER INFORMATION CONTACT:

Victoria Moreno at vmoreno@usccr.gov or by phone at 434-515-0204.

SUPPLEMENTARY INFORMATION: This meeting will be held in Spanish with English interpretation available. This meeting is available to the public through the link above. If joining only via phone, callers can expect to incur charges for calls they initiate over wireless lines, and the Commission will not refund any incurred charges. Individuals who are deaf, deafblind and hard of hearing may also follow the proceedings by first calling the Federal Relay Service at 1-800-877-8339 and providing the Service with the call-in number found through registering at the web link provided above for the meeting.

Members of the public are entitled to make comments during the open period at the end of the meeting. Members of the public may also submit written comments; the comments must be received in the Regional Programs Unit within 30 days following the respective meeting. Written comments may be emailed to Victoria Moreno at vmoreno@usccr.gov. All written comments received will be available to the public.

Persons who desire additional information may contact the Regional Programs Unit at (202) 809–9618. Records and documents discussed during the meeting will be available for public viewing as they become available at the www.facadatabase.gov. Persons interested in the work of this advisory committee are advised to go to the Commission's website, www.usccr.gov, or to contact the Regional Programs Unit at the above phone number or email address.

Agenda

Wednesday, December 14, 2022; 1 p.m. (AT)

1. Welcome & Roll Call
2. Committee Discussion on Project Proposal on the Civil Rights Impacts of the Insular Cases in Puerto Rico
3. Next Steps
4. Public Comment
5. Other Business
6. Adjourn

Dated: November 17, 2022.

David Mussatt,

Supervisory Chief, Regional Programs Unit.

[FR Doc. 2022–25417 Filed 11–21–22; 8:45 am]

BILLING CODE 6335–01–P

COMMISSION ON CIVIL RIGHTS

Notice of Public Meetings of the Arkansas Advisory Committee

AGENCY: U.S. Commission on Civil Rights.

ACTION: Announcement of meeting.

SUMMARY: Notice is hereby given, pursuant to the provisions of the rules and regulations of the U.S. Commission on Civil Rights (Commission) and the Federal Advisory Committee Act that the Arkansas Advisory Committee (Committee) will hold a virtual (online) meeting Monday, December 5, 2022 at 12 p.m. Central Time. The purpose of the meeting is for the Committee to vote to discuss completion of the Committee's report on IDEA Compliance and Implementation in Arkansas Schools.

DATES: The meeting will be held on Monday, December 5, 2022 at 12 p.m. Central time.

Web Access (Audio/Visual): Register at: <http://bit.ly/3E5WJrS>.

Phone Access (audio only): 833–435–1820, Meeting ID 161 694 2066.

FOR FURTHER INFORMATION CONTACT:

Melissa Wojnaroski, Designated Federal Officer, at mwojnaroski@usccr.gov or (202) 618–4158.

SUPPLEMENTARY INFORMATION: Members of the public may join online or listen

to this discussion through the above call-in number. An open comment period will be provided to allow members of the public to make a statement as time allows. Callers can expect to incur regular charges for calls they initiate over wireless lines, according to their wireless plan. The Commission will not refund any incurred charges. Individuals who are deaf, deafblind and hard of hearing may also follow the proceedings by first calling the Federal Relay Service at 1–800–877–8339 and providing the Service with the conference call number and conference ID number.

Members of the public are entitled to submit written comments; the comments must be received in the regional office within 30 days following the meeting. Written comments may be emailed to Melissa Wojnaroski at mwojnaroski@usccr.gov.

Records generated from this meeting may be inspected and reproduced at the Regional Programs Unit Office, as they become available, both before and after the meeting. Records of the meeting will be available via www.facadatabase.gov under the Commission on Civil Rights, Arkansas Advisory Committee link. Persons interested in the work of this Committee are directed to the Commission's website, <http://www.usccr.gov>, or may contact the Regional Programs Unit at the above email or street address.

Agenda

- I. Welcome & Roll Call
- III. Committee Discussion: IDEA Compliance and Implementation in Arkansas Schools
- IV. Next Steps
- V. Public Comment
- VI. Adjournment

Dated: November 17, 2022.

David Mussatt,

Supervisory Chief, Regional Programs Unit.

[FR Doc. 2022–25419 Filed 11–21–22; 8:45 am]

BILLING CODE 6335–01–P

DEPARTMENT OF COMMERCE

Foreign-Trade Zones Board

[B–53–2022]

Foreign-Trade Zone (FTZ) 126—Reno, Nevada; Notification of Proposed Production Activity Tesla, Inc.; Battery Products, Electric Motors, and Energy Storage Products McCarren and Sparks, Nevada

Tesla, Inc., submitted a notification of proposed production activity to the FTZ Board (the Board) for its facilities in McCarren and Sparks, Nevada within Subzone 126D. The notification

conforming to the requirements of the Board's regulations (15 CFR 400.22) was received on November 9, 2022.

Pursuant to 15 CFR 400.14(b), FTZ production activity would be limited to the specific foreign-status material(s)/ component(s) described in the submitted notification (summarized below) and subsequently authorized by the Board. The benefits that may stem from conducting production activity under FTZ procedures are explained in the background section of the Board's website—accessible via www.trade.gov/ftz. The proposed material(s)/ component(s) would be added to the production authority that the Board previously approved for the operation, as reflected on the Board's website.

The proposed foreign-status materials and components include aluminum alloy coil and aluminum tab (duty rate ranges from 3.0 to 5.7%). The request indicates that certain materials/ components are subject to duties under Section 232 of the Trade Expansion Act of 1962 (Section 232) or Section 301 of the Trade Act of 1974 (Section 301), depending on the country of origin. The applicable Section 232 and Section 301 decisions require subject merchandise to be admitted to FTZs in privileged foreign status (19 CFR 146.41).

Public comment is invited from interested parties. Submissions shall be addressed to the Board's Executive Secretary and sent to: ftz@trade.gov. The closing period for their receipt is January 3, 2023.

A copy of the notification will be available for public inspection in the "Online FTZ Information System" section of the Board's website.

For further information, contact Juanita Chen at juanita.chen@trade.gov.

Dated: November 16, 2022.

Andrew McGilvray,

Executive Secretary.

[FR Doc. 2022–25370 Filed 11–21–22; 8:45 am]

BILLING CODE 3510–DS–P

DEPARTMENT OF COMMERCE

Bureau of Industry and Security

Agency Information Collection Activities; Submission to the Office of Management and Budget (OMB) for Review and Approval; Comment Request; Report of Requests for Restrictive Trade Practice or Boycott

AGENCY: Bureau of Industry and Security, Commerce.

ACTION: Notice of information collection, request for comment.

SUMMARY: The Department of Commerce, in accordance with the Paperwork Reduction Act of 1995 (PRA), invites the general public and other Federal agencies to comment on proposed, and continuing information collections, which helps us assess the impact of our information collection requirements and minimize the public's reporting burden. The purpose of this notice is to allow for 60 days of public comment preceding submission of the collection to OMB.

DATES: To ensure consideration, comments regarding this proposed information collection must be received on or before January 23, 2023.

ADDRESSES: Interested persons are invited to submit comments by email to Mark Crace, IC Liaison, Bureau of Industry and Security, at mark.crace@bis.doc.gov or to PRAComments@doc.gov. Please reference OMB Control Number 0694-0012 in the subject line of your comments. Do not submit Confidential Business Information or otherwise sensitive or protected information.

FOR FURTHER INFORMATION CONTACT: Requests for additional information or specific questions related to collection activities should be directed to Mark Crace, IC Liaison, Bureau of Industry and Security, phone 202-482-8093 or by email at mark.crace@bis.doc.gov.

SUPPLEMENTARY INFORMATION:

I. Abstract

This information is used to monitor requests for participation in foreign boycotts against countries friendly to the U.S. The information is analyzed to note changing trends and to decide upon appropriate action to be taken to carry out the United States' policy of discouraging United States persons from participating in foreign restrictive trade practices and boycotts directed against countries friendly to the United States.

II. Method of Collection

Electronic.

III. Data

OMB Control Number: 0694-0012.

Form Number(s): None.

Type of Review: Regular submission, extension of a current information collection.

Affected Public: Business or other for-profit organizations.

Estimated Number of Respondents: 412.

Estimated Time per Response: 1 hour to 1 hour and 30 minutes.

Estimated Total Annual Burden Hours: 482.

Estimated Total Annual Cost to Public: 0.

Respondent's Obligation: Voluntary.
Legal Authority: EAR Sections 764.5, and 764.7.

IV. Request for Comments

We are soliciting public comments to permit the Department/Bureau to: (a) Evaluate whether the proposed information collection is necessary for the proper functions of the Department, including whether the information will have practical utility; (b) Evaluate the accuracy of our estimate of the time and cost burden for this proposed collection, including the validity of the methodology and assumptions used; (c) Evaluate ways to enhance the quality, utility, and clarity of the information to be collected; and (d) Minimize the reporting burden on those who are to respond, including the use of automated collection techniques or other forms of information technology.

Comments that you submit in response to this notice are a matter of public record. We will include or summarize each comment in our request to OMB to approve this ICR. Before including your address, phone number, email address, or other personal identifying information in your comment, you should be aware that your entire comment—including your personal identifying information—may be made publicly available at any time. While you may ask us in your comment to withhold your personal identifying information from public review, we cannot guarantee that we will be able to do so.

Sheleen Dumas,

Department PRA Clearance Officer, Office of the Chief Information Officer, Commerce Department.

[FR Doc. 2022-25436 Filed 11-21-22; 8:45 am]

BILLING CODE 3510-33-P

DEPARTMENT OF COMMERCE

Bureau of Industry and Security

Agency Information Collection Activities; Submission to the Office of Management and Budget (OMB) for Review and Approval; Comment Request; Foreign Availability Procedures

AGENCY: Bureau of Industry and Security, Commerce.

ACTION: Notice of information collection, request for comment.

SUMMARY: The Department of Commerce, in accordance with the Paperwork Reduction Act of 1995 (PRA), invites the general public and other Federal agencies to comment on

proposed, and continuing information collections, which helps us assess the impact of our information collection requirements and minimize the public's reporting burden. The purpose of this notice is to allow for 60 days of public comment preceding submission of the collection to OMB.

DATES: To ensure consideration, comments regarding this proposed information collection must be received on or before January 23, 2023.

ADDRESSES: Interested persons are invited to submit comments by email to Mark Crace, IC Liaison, Bureau of Industry and Security, at mark.crace@bis.doc.gov or to PRAComments@doc.gov. Please reference OMB Control Number 0694-0004 in the subject line of your comments. Do not submit Confidential Business Information or otherwise sensitive or protected information.

FOR FURTHER INFORMATION CONTACT:

Requests for additional information or specific questions related to collection activities should be directed to Mark Crace, IC Liaison, Bureau of Industry and Security, phone 202-482-8093 or by email at mark.crace@bis.doc.gov.

SUPPLEMENTARY INFORMATION:

I. Abstract

This information is collected in order to respond to requests by Congress and industry to make foreign availability determinations in accordance with Section 768 of the Export Administration Regulations. Exporters are urged to voluntarily submit data to support the contention that items controlled for export for national security reasons are available-in-fact, from a non-U.S. source, in sufficient quantity and of comparable quality so as to render the control ineffective.

II. Method of Collection

Electronic.

III. Data

OMB Control Number: 0694-0004.

Form Number(s): None.

Type of Review: Regular submission, extension of a current information collection.

Affected Public: Business or other for-profit organizations.

Estimated Number of Respondents: 2.

Estimated Time per Response: 255.

Estimated Total Annual Burden

Hours: 510.

Estimated Total Annual Cost to Public: 0.

Respondent's Obligation: Voluntary.

Legal Authority: Section 1754(a)(6) of the Export Control Reform Act (ECRA).

IV. Request for Comments

We are soliciting public comments to permit the Department/Bureau to: (a) Evaluate whether the proposed information collection is necessary for the proper functions of the Department, including whether the information will have practical utility; (b) Evaluate the accuracy of our estimate of the time and cost burden for this proposed collection, including the validity of the methodology and assumptions used; (c) Evaluate ways to enhance the quality, utility, and clarity of the information to be collected; and (d) Minimize the reporting burden on those who are to respond, including the use of automated collection techniques or other forms of information technology.

Comments that you submit in response to this notice are a matter of public record. We will include or summarize each comment in our request to OMB to approve this ICR. Before including your address, phone number, email address, or other personal identifying information in your comment, you should be aware that your entire comment—including your personal identifying information—may be made publicly available at any time. While you may ask us in your comment to withhold your personal identifying information from public review, we cannot guarantee that we will be able to do so.

Sheleen Dumas,

Department PRA Clearance Officer, Office of the Chief Information Officer, Commerce Department.

[FR Doc. 2022–25432 Filed 11–21–22; 8:45 am]

BILLING CODE 3510–33–P

DEPARTMENT OF COMMERCE

International Trade Administration

[A–570–890]

Wooden Bedroom Furniture From the People's Republic of China: Initiation of Antidumping Duty Changed Circumstances Review

AGENCY: Enforcement and Compliance, International Trade Administration, Department of Commerce.

SUMMARY: In response to a request from Golden Well International (HK), Ltd. (Golden Well) and Zhangzhou XMB Home Technology Co., Ltd. (Zhangzhou XMB), the U.S. Department of Commerce (Commerce) is initiating a changed circumstances review (CCR) of the antidumping duty (AD) order on wooden bedroom furniture (WBF) from the People's Republic of China (China) to determine whether Zhangzhou XMB

is the successor-in-interest to Zhangzhou XYM Furniture Product Co., Ltd. (Zhangzhou XYM).

DATES: Applicable November 22, 2022.

FOR FURTHER INFORMATION CONTACT: Thomas Martin, AD/CVD Operations, Office IV, Enforcement and Compliance, International Trade Administration, U.S. Department of Commerce, 1401 Constitution Avenue NW, Washington, DC 20230; telephone: (202) 482–3936.

SUPPLEMENTARY INFORMATION:

Background

On January 4, 2005, Commerce published in the **Federal Register** an amended final less-than-fair-value determination and AD order on WBF from China.¹ On August 17, 2009, Commerce published in the **Federal Register** the final results of an administrative review and new shipper reviews of the AD order on WBF from China, in which it determined that the exporter/producer combination of Golden Well and Zhangzhou XYM established its eligibility for a separate combination rate.²

On October 5, 2022, Golden Well and Zhangzhou XMB notified Commerce that Zhangzhou XYM changed its name to Zhangzhou XMB and requested that Commerce conduct a CCR to determine that Zhangzhou XMB is the successor-in-interest to Zhangzhou XYM.³ We received no comments from interested parties regarding the CCR Request.

Scope of the Order

The merchandise covered by the Order is WBF. For a complete description of the scope of the Order, see the appendix to this notice.

Initiation of CCR

Pursuant to section 751(b)(1)(A) of the Tariff Act of 1930, as amended (the Act), and 19 CFR 351.216(d), Commerce will conduct a CCR upon receipt of a request from an interested party for a review of an AD order which shows changed circumstances sufficient to warrant a review of the order. Commerce conducts CCRs to address, among other things, the applicability of cash deposit rates

after there have been changes in the name or structure of a respondent, such as a merger or spinoff (*i.e.*, a successor-in-interest determination).⁴ Golden Well and Zhangzhou XMB provided information regarding the name change sufficient to warrant the initiation of a CCR.⁵ Therefore, in accordance with section 751(b)(1)(A) of the Act and 19 CFR 351.216(d), we are initiating a CCR to determine whether Zhangzhou XMB is the successor-in-interest to Zhangzhou XYM.

In successor-in-interest CCRs, Commerce examines, among other things, whether there have been changes in a company's: (1) management; (2) facilities; (3) suppliers; or (4) customers since a name change to determine whether the company under the new name is essentially the same as it was under the prior name. While no single factor or combination of factors necessarily provides a dispositive indication of a successor-in-interest relationship, generally Commerce considers the new company to be the successor to the previous company if the new company's resulting operation is not materially dissimilar to that of its predecessor. Thus, if the record evidence demonstrates that, with respect to the production and sale of the subject merchandise, the new company operates as the same business entity as the predecessor company, Commerce may assign the new company the cash deposit rate of its predecessor.

Pursuant to 19 CFR 351.221(c)(3)(ii), Commerce may combine the notices of initiation and preliminary results of a CCR into a single notice if it concludes that expedited action is warranted. We have determined that it is appropriate to further consider, and potentially seek additional information regarding, certain of the factors noted above that Commerce examines in successor-in-interest CCRs. Therefore, we have determined that expedited action is not warranted and we have not combined the notice of preliminary results of the CCR with this notice. Commerce intends to publish notice of the preliminary results of this CCR in the **Federal Register** in accordance with 19 CFR 351.221(b)(4) and (c)(3)(i). Pursuant to 19 CFR 351.221(b)(4)(ii), interested

¹ See Notice of Amended Final Determination of Sales at Less Than Fair Value and Antidumping Duty Order: Wooden Bedroom Furniture from the People's Republic of China, 70 FR 329 (January 4, 2005) (Order).

² See Wooden Bedroom Furniture from the People's Republic of China: Final Results of Antidumping Duty Administrative Review and New Shipper Reviews, 74 FR 41374, 41380 (August 17, 2009).

³ See Golden Well and Zhangzhou XMB's Letter, "Wooden Bedroom Furniture from the People's Republic of China; Request for Changed Circumstances Review (A–570–890)," dated October 5, 2022 (CCR Request).

⁴ See, e.g., *Diamond Sawblades and Parts Thereof from the People's Republic of China: Initiation and Preliminary Results of Antidumping Duty Changed Circumstances Review*, 82 FR 51605, 51606 (November 7, 2017), unchanged in *Diamond Sawblades and Parts Thereof from the People's Republic of China: Final Results of Antidumping Duty Changed Circumstances Review*, 82 FR 60177 (December 19, 2017).

⁵ See 19 CFR 351.216(d).

parties will have an opportunity to comment on the preliminary results.

Unless extended, Commerce intends to issue the final results of this CCR within 270 days after the date of initiation, in accordance with 19 CFR 351.216(e).

Notification to Interested Parties

This notice is published in accordance with section 751(b)(1) of the Act, and 19 CFR 351.216(b) and 19 CFR 351.221(b)(1).

Dated: November 16, 2022.

James Maeder,

Deputy Assistant Secretary for Antidumping and Countervailing Duty Operations.

Appendix—Scope of the Order

The product covered by the *Order* is wooden bedroom furniture. Wooden bedroom furniture is generally, but not exclusively, designed, manufactured, and offered for sale in coordinated groups, or bedrooms, in which all of the individual pieces are of approximately the same style and approximately the same material and/or finish. The subject merchandise is made substantially of wood products, including both solid wood and also engineered wood products made from wood particles, fibers, or other wooden materials such as plywood, strand board, particle board, and fiberboard, with or without wood veneers, wood overlays, or laminates, with or without non-wood components or trim such as metal, marble, leather, glass, plastic, or other resins, and whether or not assembled, completed, or finished.

The subject merchandise includes the following items: (1) wooden beds such as loft beds, bunk beds, and other beds; (2) wooden headboards for beds (whether stand-alone or attached to side rails), wooden footboards for beds, wooden side rails for beds, and wooden canopies for beds; (3) night tables, night stands, dressers, commodes, bureaus, mule chests, gentlemen's chests, bachelor's chests, lingerie chests, wardrobes, vanities, chessers, chifforobes, and wardrobe-type cabinets; (4) dressers with framed glass mirrors that are attached to, incorporated in, sit on, or hang over the dresser; (5) chests-on-chests,⁶ highboys,⁷ lowboys,⁸ chests of drawers,⁹

chests,¹⁰ door chests,¹¹ chiffoniers,¹² hutches,¹³ and armoires;¹⁴ (6) desks,

¹⁰ A chest is typically a case piece taller than it is wide featuring a series of drawers and with or without one or more doors for storing clothing. The piece can either include drawers or be designed as a large box incorporating a lid.

¹¹ A door chest is typically a chest with hinged doors to store clothing, whether or not containing drawers. The piece may also include shelves for televisions and other entertainment electronics.

¹² A chiffonier is typically a tall and narrow chest of drawers normally used for storing undergarments and lingerie, often with mirror(s) attached.

¹³ A hutch is typically an open case of furniture with shelves that typically sits on another piece of furniture and provides storage for clothes.

¹⁴ An armoire is typically a tall cabinet or wardrobe (typically 50 inches or taller), with doors, and with one or more drawers (either exterior below or above the doors or interior behind the doors), shelves, and/or garment rods or other apparatus for storing clothes. Bedroom armoires may also be used to hold television receivers and/or other audiovisual entertainment systems.

¹⁵ As used herein, bentwood means solid wood made pliable. Bentwood is wood that is brought to a curved shape by bending it while made pliable with moist heat or other agency and then set by cooling or drying. See CBP's Headquarters Ruling Letter 043859, dated May 17, 1976.

¹⁶ Any armoire, cabinet, or other accent item for the purpose of storing jewelry, not to exceed 24 inches in width, 18 inches in depth, and 49 inches in height, including a minimum of 5 lined drawers lined with felt or felt-like material, at least one side door or one front door (whether or not the door is lined with felt or felt-like material), with necklace hangers, and a flip-top lid with inset mirror. See Memorandum, "Jewelry Armoires and Cheval Mirrors in the Antidumping Duty Investigation of Wooden Bedroom Furniture from the People's Republic of China," dated August 31, 2004; see also *Wooden Bedroom Furniture from the People's Republic of China: Final Changed Circumstances Review, and Determination To Revoke Order in Part*, 71 FR 38621 (July 7, 2006).

¹⁷ Cheval mirrors are any framed, tiltable mirror with a height in excess of 50 inches that is mounted on a floorstanding, hinged base. Additionally, the scope of the Order excludes combination cheval mirror/jewelry cabinets. The excluded merchandise is an integrated piece consisting of a cheval mirror, i.e., a framed tiltable mirror with a height in excess of 50 inches, mounted on a floor-standing, hinged base, the cheval mirror serving as a door to a cabinet back that is integral to the structure of the mirror and which constitutes a jewelry cabinet line with fabric, having necklace and bracelet hooks, mountings for rings and shelves, with or without a working lock and key to secure the contents of the jewelry cabinet back to the cheval mirror, and no drawers anywhere on the integrated piece. The fully assembled piece must be at least 50 inches in height, 14.5 inches in width, and 3 inches in depth. See *Wooden Bedroom Furniture from the People's Republic of China: Final Changed Circumstances Review and Determination To Revoke Order in Part*, 72 FR 948 (January 9, 2007).

¹⁸ Metal furniture parts and unfinished furniture parts made of wood products (as defined above) that are not otherwise specifically named in this scope (i.e., wooden headboards for beds, wooden footboards for beds, wooden side rails for beds, and wooden canopies for beds) and that do not possess the essential character of wooden bedroom

computer stands, filing cabinets, book cases, or writing tables that are attached to or incorporated in the subject merchandise; and (7) other bedroom furniture consistent with the above list.

The scope of the *Order* excludes the following items: (1) seats, chairs, benches, couches, sofas, sofa beds, stools, and other seating furniture; (2) mattresses, mattress supports (including box springs), infant cribs, water beds, and futon frames; (3) office furniture, such as desks, stand-up desks, computer cabinets, filing cabinets, credenzas, and bookcases; (4) dining room or kitchen furniture such as dining tables, chairs, servers, sideboards, buffets, corner cabinets, china cabinets, and china hutches; (5) other non-bedroom furniture, such as television cabinets, cocktail tables, end tables, occasional tables, wall systems, book cases, and entertainment systems; (6) bedroom furniture made primarily of wicker, cane, osier, bamboo or rattan; (7) side rails for beds made of metal if sold separately from the headboard and footboard; (8) bedroom furniture in which bentwood parts predominate;¹⁵ (9) jewelry armoires;¹⁶ (10) cheval mirrors;¹⁷ (11) certain metal parts;¹⁸ (12) mirrors that do not attach to, incorporate in, sit on, or hang over a dresser if they are not designed and marketed to be sold in conjunction with a dresser as part of a dresser-mirror set; (13) upholstered beds;¹⁹ (14) toyboxes;²⁰ (15) certain enclosable wall

furniture in an unassembled, incomplete, or unfinished form.

¹⁹ Upholstered beds that are completely upholstered, i.e., containing filling material and completely covered in sewn genuine leather, synthetic leather, or natural or synthetic decorative fabric. To be excluded, the entire bed (headboards, footboards, and side rails) must be upholstered except for bed feet, which may be of wood, metal, or any other material and which are no more than nine inches in height from the floor. See *Wooden Bedroom Furniture from the People's Republic of China: Final Results of Changed Circumstances Review and Determination To Revoke Order in Part*, 72 FR 7013 (February 14, 2007).

²⁰ To be excluded the toy box must: (1) be wider than it is tall; (2) have dimensions within 16 inches to 27 inches in height, 15 inches to 18 inches in depth, and 21 inches to 30 inches in width; (3) have a hinged lid that encompasses the entire top of the box; (4) not incorporate any doors or drawers; (5) have slow-closing safety hinges; (6) have air vents; (7) have no locking mechanism; and (8) comply with American Society for Testing and Materials ("ASTM") standard F963–03. Toy boxes are boxes generally designed for the purpose of storing children's items such as toys, books, and playthings. See *Wooden Bedroom Furniture from the People's Republic of China: Final Results of Changed Circumstances Review and Determination To Revoke Order in Part*, 74 FR 8506 (February 25, 2009). Further, as determined in the scope ruling memorandum, "Wooden Bedroom Furniture from the People's Republic of China: Scope Ruling on a White Toy Box," dated July 6, 2009, the dimensional ranges used to identify the toy boxes that are excluded from the *Order* apply to the box itself rather than the lid.

⁶ A chest-on-chest is typically a tall chest-of-drawers in two or more sections (or appearing to be in two or more sections), with one or two sections mounted (or appearing to be mounted) on a slightly larger chest; also known as a tallboy.

⁷ A highboy is typically a tall chest of drawers usually composed of a base and a top section with drawers, and supported on four legs or a small chest (often 15 inches or more in height).

⁸ A lowboy is typically a short chest of drawers, not more than four feet high, normally set on short legs.

⁹ A chest of drawers is typically a case containing drawers for storing clothing.

bed units;²¹ (16) certain shoe cabinets;²² and (17) certain bed bases.²³

Imports of subject merchandise are classified under subheadings 9403.50.9042 and 9403.50.9045 of the Harmonized Tariff Schedule of the United States (HTSUS) as “wooden . . . beds” and under subheading 9403.50.9080 of the HTSUS as “other . . . wooden furniture of a kind used in the bedroom.” In addition, wooden headboards for beds, wooden footboards for beds, wooden side rails for beds, and wooden canopies for beds may be entered under subheadings 9403.90.7005 or 9403.90.7080 of the HTSUS. Subject merchandise may also be entered under subheadings 9403.50.9041, 9403.60.8081, 9403.20.0018, or 9403.90.8041. Further, framed glass mirrors may be entered under subheading 7009.92.1000 or 7009.92.5000 of the HTSUS as “glass mirrors . . . framed.” The *Order* covers all wooden bedroom furniture meeting the above description, regardless of tariff classification. Although the HTSUS subheadings are provided for convenience and customs purposes, our written description of the scope of this proceeding is dispositive.

[FR Doc. 2022–25369 Filed 11–21–22; 8:45 am]

BILLING CODE 3510–DS–P

²¹ Excluded from the scope are certain enclosable wall bed units, also referred to as murphy beds, which are composed of the following three major sections: (1) a metal wall frame, which attaches to the wall and uses coils or pistons to support the metal mattress frame; (2) a metal frame, which has euro slats for supporting a mattress and two legs that pivot; and (3) wood panels, which attach to the metal wall frame and/or the metal mattress frame to form a cabinet to enclose the wall bed when not in use. Excluded enclosable wall bed units are imported in ready to assemble format with all parts necessary for assembly. Enclosable wall bed units do not include a mattress. Wood panels of enclosable wall bed units, when imported separately, remain subject to the *Order*.

²² Excluded from the scope are certain shoe cabinets 31.5–33.5 inches wide by 15.5–17.5 inches deep by 34.5–36.5 inches high. They are designed strictly to store shoes, which are intended to be aligned in rows perpendicular to the wall along which the cabinet is positioned. Shoe cabinets do not have drawers, rods, or other indicia for the storage of clothing other than shoes. The cabinets are not designed, manufactured, or offered for sale in coordinated groups or sets and are made substantially of wood, have two to four shelves inside them, and are covered by doors. The doors often have blinds that are designed to allow air circulation and release of bad odors. The doors themselves may be made of wood or glass. The depth of the shelves does not exceed 14 inches. Each shoe cabinet has doors, adjustable shelving, and ventilation holes.

²³ Excluded from the scope are certain bed bases consisting of: (1) a wooden box frame; (2) three wooden cross beams and one perpendicular center wooden support beam; and (3) wooden slats over the beams. These bed bases are constructed without inner springs and/or coils and do not include a headboard, footboard, side rails, or mattress. The bed bases are imported unassembled.

DEPARTMENT OF COMMERCE

International Trade Administration

[C–570–105]

Carbon and Alloy Steel Threaded Rod From the People’s Republic of China: Notice of Final Results of Countervailing Duty Administrative Review; 2019–2020; Correction

AGENCY: Enforcement and Compliance, International Trade Administration, Department of Commerce.

ACTION: Notice; correction.

SUMMARY: On November 7, 2022, the U.S. Department of Commerce (Commerce) published a notice in the *Federal Register* regarding the final results of the 2019–2020 administrative review of the countervailing duty (CVD) order on carbon and alloy steel threaded rod from the People’s Republic of China. This notice inadvertently misspelled the name of a company that is a cross-owned affiliate of a company subject to the CVD review.

FOR FURTHER INFORMATION CONTACT:

Allison Hollander or Thomas Schauer, AD/CVD Operations, Office I, Enforcement and Compliance, International Trade Administration, U.S. Department of Commerce, 1401 Constitution Avenue NW, Washington, DC 20230; telephone: (202) 482–2805 or (202) 482–0410, respectively.

SUPPLEMENTARY INFORMATION:

Correction

In the *Federal Register* of November 7, 2022, in footnote 2 of the chart on page 67017, Commerce misspelled the name of Haiyan County Brother Paper Industry Co., Ltd. (Brother Paper), as “Haiyan County Brothers Paper Industry Co., Ltd.”

Background

In the *Final Results* of the CVD administrative review covering the 2019–2020 period of review, Commerce calculated a rate for Zhejiang Junyue Standard Part Co., Ltd (Junyue).¹ Brother Paper submitted a response to our questionnaire, identifying itself as “Haiyan County Brother Paper Industry Co., Ltd.,” in its narrative as well as in its business license and articles of association.² In the *Final Results*, we

¹ See *Carbon and Alloy Steel Threaded Rod from the People’s Republic of China: Final Results of Countervailing Duty Administrative Review; 2019–2020*, 87 FR 67016, 67017 (November 7, 2022) (*Final Results*).

² See Brother Paper’s Letter, “Carbon and Alloy Steel Threaded Rod from the People’s Republic of China—Section III Questionnaire,” dated September 20, 2021, at 1 and Exhibit 3.

determined that Brother Paper is cross-owned with Junyue.³ With the issuance of this notice of correction, we confirm that the correct spelling of Brother Paper’s name is “Haiyan County Brother Paper Industry Co., Ltd.”

Notification to Interested Parties

This notice is issued and published in accordance with sections 751(a)(1) and 777(i) of the Tariff Act of 1930, as amended.

Dated: November 16, 2022.

Lisa W. Wang,

Assistant Secretary for Enforcement and Compliance.

[FR Doc. 2022–25407 Filed 11–21–22; 8:45 am]

BILLING CODE 3510–DS–P

DEPARTMENT OF COMMERCE

International Trade Administration

University of South Florida, et al.; Application(s) for Duty-Free Entry of Scientific Instruments

Pursuant to Section 6(c) of the Educational, Scientific and Cultural Materials Importation Act of 1966 (Pub. L. 89–651, as amended by Pub. L. 106–36; 80 Stat. 897; 15 CFR part 301), we invite comments on the question of whether instruments of equivalent scientific value, for the purposes for which the instruments shown below are intended to be used, are being manufactured in the United States.

Comments must comply with 15 CFR 301.5(a)(3) and (4) of the regulations and be postmarked on or before December 12, 2022. Address written comments to Statutory Import Programs Staff, Room 3720, U.S. Department of Commerce, Washington, DC 20230. Please also email a copy of those comments to Dianne.Hanshaw@trade.gov.

Docket Number: 23–001. Applicant: University of Florida, Department of Medical Engineering, 4202 E Fowler Avenue, ENG 030, Tampa, FL 33620. Instrument: Bowl-shaped 1024 ultrasound transducer array. Manufacturer: Hebei ULSO Tech Company, Ltd., China. Intended Use: The instrument will be used to build up a real-time three-dimensional (3D) Photoacoustic Tomography (PAT) imaging system for a National Institutes of Health (NIH) granted research project. The goal of this research is to develop a novel photoacoustic imaging approach that will allow non-invasive, simultaneous three-dimensional visualization of all the embryos in mouse utero and track their birth/

³ See *Final Results*, 87 FR at 67017.

adulthood longitudinally to study the association between maternal alcohol exposure induced fetal hemodynamic changes and the outcome of fetal alcohol spectrum disorder (FASD) after birth. Justification for Duty-Free Entry: According to the applicant, there are no instruments of the same general category manufactured in the United States. Application accepted by Commissioner of Customs: March 31, 2022.

Docket Number: 23–002. Applicant: University of South Florida, Department of Medical Engineering, 4202 E Fowler Avenue, ENG 030, Tampa, FL 33620. Instrument: Annular ring 256 ultrasound transducer array. Manufacturer: Hebei ULSO Tech Company, Ltd., China. Intended Use: This instrument will be used to build up a real-time two-dimensional (2D) Photoacoustic Tomography (PAT) imaging system and a Thermoacoustic Tomography (TAT) imaging system, in which a high-quality transducer probe is the key part. The ultrasound signal generated from the tissue by absorption of pulsed laser in PAT or of microwave source in TAT will be collected by transducer elements from different angles. Using specific imaging reconstruction algorithm, the 2D images of the tissue could be reconstructed. The new PAT and TAT imaging system based on this new transducer probe will be used to study the neural activity and hemodynamic response in the brain of patients with epilepsy. Justification for Duty-Free Entry: According to the applicant, there are no instruments of the same general category manufactured in the United States. Application accepted by Commissioner of Customs: March 31, 2022.

Docket Number: 23–003. Applicant: University of South Florida, Department of Medical Engineering, 4202 E. Fowler Avenue, ENG 030, Tampa, FL 33620.

Instrument: L-band Microwave source. Manufacturer: Hebei ULSO Tech Co., Ltd., China. Intended Use: This instrument will be used to build up a real-time two-dimensional (2D) thermoacoustic tomography imaging (TAT) system. It will work with the annular ring-shaped transducer probe (another order). This novel TAT imaging system will be applied in the research of gene therapy, cancer-diagnosis and so on. This new L-band microwave has different center frequency and much stronger output power, will provide the capability to penetrate deeper in the tissue with better image quality. Justification for Duty-Free Entry: According to the applicant, there are no instruments of the same general category manufactured in the United

States. Application accepted by Commissioner of Customs: March 31, 2022.

Dated: November 16, 2022.

Richard Herring,
Director, Subsidies Enforcement, Enforcement and Compliance.

[FR Doc. 2022–25371 Filed 11–21–22; 8:45 am]

BILLING CODE 3510–DS–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

[RTID 0648–XC570]

Pacific Fishery Management Council; Public Meeting

AGENCY: National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce.

ACTION: Notice of public online meeting.

SUMMARY: The Groundfish Subcommittee of the Pacific Fishery Management Council's (Pacific Council) Scientific and Statistical Committee (SSC) will hold a virtual meeting to update the Accepted Practices Guidelines for Groundfish Stock Assessments document. The SSC Groundfish Subcommittee meeting is open to the public.

DATES: The SSC Groundfish Subcommittee's online meeting will be held Monday, December 12, 2022, beginning at 1 p.m. and continuing until 5 p.m., Pacific Time or until business for the day has been completed.

ADDRESSES: The SSC Groundfish Subcommittee's meeting will be an online meeting. Specific meeting information, including directions on how to join the meeting and system requirements, will be provided in the meeting announcement on the Pacific Council's website (see www.pcouncil.org). You may send an email to Mr. Kris Kleinschmidt (kris.kleinschmidt@noaa.gov) or contact him at (503) 820–2412 for technical assistance.

Council address: Pacific Fishery Management Council, 7700 NE Ambassador Place, Suite 101, Portland, OR 97220.

FOR FURTHER INFORMATION CONTACT: Marlene A. Bellman, Staff Officer, Pacific Council; telephone: (503) 820–2414, email: marlene.bellman@noaa.gov.

SUPPLEMENTARY INFORMATION: The purpose of the SSC Groundfish Subcommittee's meeting is to update best practices for conducting groundfish

stock assessments. Recommendations of SSC Groundfish Subcommittee members will inform the Accepted Practices Guidelines for Stock Assessments in 2023 and 2024, which is a compilation of guidelines for groundfish stock assessment scientists. The updated version of the Accepted Practices Guidelines for Stock Assessments will be posted on the Pacific Council's website shortly after the meeting.

No management actions will be decided by the SSC Groundfish Subcommittee. The SSC Groundfish Subcommittee members' role will be development of recommendations for consideration by West Coast groundfish stock assessment scientists.

Although nonemergency issues not contained in the meeting agendas may be discussed, those issues may not be the subject of formal action during this meeting. Action will be restricted to those issues specifically listed in this notice and any issues arising after publication of this notice that require emergency action under Section 305(c) of the Magnuson-Stevens Fishery Conservation and Management Act, provided the public has been notified of the intent of the SSC Groundfish Subcommittee to take final action to address the emergency.

Special Accommodations

Requests for sign language interpretation or other auxiliary aids should be directed to Mr. Kris Kleinschmidt (kris.kleinschmidt@noaa.gov; (503) 820–2412) at least 10 days prior to the meeting date.

Dated: November 17, 2022.

Diane M. DeJames-Daly,
Acting Deputy Director, Office of Sustainable Fisheries, National Marine Fisheries Service.

[FR Doc. 2022–25387 Filed 11–21–22; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

[RTID 0648–XC563]

Marine Mammals; File No. 24334

AGENCY: National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce.

ACTION: Notice; receipt of application for permit amendment.

SUMMARY: Notice is hereby given that the Alaska Department of Fish and Game, P.O. Box 25526, Juneau, AK 99802, (Responsible Party: Lori

Quakenbush), has applied for an amendment to Scientific Research Permit No. 24334.

DATES: Written, telefaxed, or email comments must be received on or before December 22, 2022.

ADDRESSES: The application and related documents are available for review by selecting “Records Open for Public Comment” from the “Features” box on the Applications and Permits for Protected Species (APPS) home page, <https://apps.nmfs.noaa.gov>, and then selecting File No. 24334 mod 1 from the list of available applications. These documents are also available upon written request via email to NMFS.Pr1Comments@noaa.gov.

Written comments on this application should be submitted via email to NMFS.Pr1Comments@noaa.gov. Please include File No. 24334 in the subject line of the email comment.

Those individuals requesting a public hearing should submit a written request via email to NMFS.Pr1Comments@noaa.gov. The request should set forth the specific reasons why a hearing on this application would be appropriate.

FOR FURTHER INFORMATION CONTACT: Amy Hapeman or Sara Young, (301) 427-8401.

SUPPLEMENTARY INFORMATION: The subject amendment to Permit No. 24334 is requested under the authority of the Marine Mammal Protection Act of 1972, as amended (16 U.S.C. 1361 *et seq.*), the regulations governing the taking and importing of marine mammals (50 CFR part 216), the Endangered Species Act of 1973, as amended (16 U.S.C. 1531 *et seq.*), and the regulations governing the taking, importing, and exporting of endangered and threatened species (50 CFR parts 222-226).

Permit No. 24334, issued on July 13, 2021 (86 FR 43630, August 10, 2021), authorizes the permit holder to conduct research on five whale species in the Bering, Chukchi, and Beaufort seas (U.S. and international waters) adjacent to Alaska. Researchers may conduct vessel surveys for tagging (invasive tags or suction cup tags), biopsy sampling, photo-identification, and unmanned aircraft system (UAS) surveys for all species. Researchers also may conduct manned aerial surveys and captures for tagging with biological sample collection of four beluga whale (*Delphinapterus leucas*) stocks and export and import of skin and blubber for the target species. Non-target seals and beluga whales may be unintentionally harassed, and seals may be incidentally captured during research activities. Up to three unintentional

beluga mortalities may occur during captures over the duration of the permit.

The permit holder is requesting the permit be amended to authorize the annual receipt, collection, import, or export of parts from up to 300 beluga whales and up to 50 other unidentified cetaceans (any species). Sources of foreign and domestic samples may include subsistence harvests, captive animals, other authorized researchers or curated collections, bycatch from legal commercial fishing operations, cetaceans killed by killer whales, parts that are sloughed, excreted or discharged naturally by living cetaceans, and foreign stranded animals. No take or harassment of live animals would be authorized. The amendment would be valid for the duration of the permit, which is set to expire on April 30, 2026.

In compliance with the National Environmental Policy Act of 1969 (42 U.S.C. 4321 *et seq.*), an initial determination has been made that the activity proposed is categorically excluded from the requirement to prepare an environmental assessment or environmental impact statement.

Concurrent with the publication of this notice in the **Federal Register**, NMFS is forwarding copies of this application to the Marine Mammal Commission and its Committee of Scientific Advisors.

Julia M. Harrison,

Chief, Permits and Conservation Division,
Office of Protected Resources, National
Marine Fisheries Service.

[FR Doc. 2022-25430 Filed 11-21-22; 8:45 am]

BILLING CODE 3510-22-P

DEPARTMENT OF COMMERCE

United States Patent and Trademark Office

Agency Information Collection Activities; Submission to the Office of Management and Budget (OMB) for Review and Approval; Comment Request; Deposit of Biological Materials

AGENCY: United States Patent and Trademark Office, Department of Commerce.

ACTION: Notice of information collection; request for comment.

SUMMARY: The United States Patent and Trademark Office (USPTO), as required by the Paperwork Reduction Act of 1995, invites comments on the extension and revision of an existing information collection: 0651-0022 Deposit of Biological Materials. The

purpose of this notice is to allow 60 days for public comment preceding submission of the information collection to OMB.

DATES: To ensure consideration, comments regarding this information collection must be received on or January 23, 2023.

ADDRESSES: Interested persons are invited to submit written comments by any of the following methods. Do not submit Confidential Business Information or otherwise sensitive or protected information.

- **Email:** InformationCollection@uspto.gov. Include “0651-0022 comment” in the subject line of the message.

- **Federal Rulemaking Portal:** <http://www.regulations.gov>.

- **Mail:** Justin Isaac, Office of the Chief Administrative Officer, United States Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313-1450.

FOR FURTHER INFORMATION CONTACT:

Requests for additional information should be directed to Parikha Mehta, Senior Legal Advisor, United States Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313-1450; by telephone at 571-272-3248; or by email at parikha.mehta@uspto.gov with “0651-0022 comment” in the subject line. Additional information about this information collection is also available at <http://www.reginfo.gov> under “Information Collection Review.”

SUPPLEMENTARY INFORMATION:

I. Abstract

This collection covers information from patent applicants who seek to deposit biological materials as part of a patent application according to 37 CFR 1.801-1.809. The information collected from such patent applicants consists of information and documentation demonstrating the applicant’s compliance with regulatory requirements, as well as information regarding the biological sample after it is deposited. This collection also covers applications from institutions that wish to be recognized by the USPTO as a suitable depository to receive deposits for patent application purposes. The information collection requirements for these actions are separate, as further discussed below.

A. Deposits of Biological Materials

The deposit of biological materials as part of a patent application is authorized by 35 U.S.C. 2(b)(2). The term “biological material” is defined in 37 CFR 1.801 as including material that is capable of self-replication, either

directly or indirectly. When an invention involves a biological material, words and figures may not sufficiently describe how to make and use the invention in a reproducible manner as required by 35 U.S.C. 112. In such cases, the inventive biological material must be known and readily available to the public or can be made or isolated without undue experimentation (see 37 CFR 1.802). In order to satisfy the “known and readily available” requirement, the biological material may be deposited in a suitable depository that has been recognized as an International Depository Authority (IDA) established under the Budapest Treaty per 37 CFR 1.803(a)(1), or any other depository recognized to be suitable by the USPTO per 37 CFR 1.803(a)(2). Under the authority of 35 U.S.C. 2(b)(2), the deposit rules (37 CFR 1.801–1.809) set forth examining procedures and conditions of deposit which must be satisfied in the event a deposit is required.

In cases where a deposit of biological material that is capable of self-replication either directly or indirectly is made, and the deposit is not made under the Budapest Treaty, the USPTO collects information to determine whether the deposit meets the viability requirements of 37 CFR 1.807. This information includes a viability statement under 37 CFR 1.807, such statement identifying:

- (1) The name and address of the depository where the deposit was made,
- (2) The name and address of the depositor,
- (3) The date of the deposit,
- (4) The identity of the deposit and the accession number given by the depository,
- (5) The date of the viability test,
- (6) The procedures used to obtain a sample if the test was not done by the depository, and
- (7) A statement that the deposit is capable of reproduction.

A viability statement is not required when a deposit is made and accepted under the Budapest Treaty.

This collection also covers additional information that may be gathered by the USPTO after a biological material is deposited into the recognized depository. For example, depositors may be required to submit verification statements for biological materials deposited after the effective filing date of a patent application or written

notification that an acceptable deposit will be made. Occasionally a deposit may be lost, contaminated, or is not able to self-replicate, and a replacement or supplemental deposit needs to be made. This information collection includes a required written notification that the depositor must submit to the USPTO disclosing the particulars of such situation and request a certificate of correction by the USPTO authorizing a replacement or supplemental deposit.

There are no forms associated with the information collected by the USPTO in connection with the deposit of biological materials, however there are forms available under the Budapest Treaty for use with international depositories.

B. Depositories

Institutions that wish to be recognized by the USPTO as a suitable depository to receive deposits for patent purposes, are required by 37 CFR 1.803(b) to make a request demonstrating that they are qualified to store and test the biological materials submitted to them under patent applications (see also MPEP 2405). This collection covers the information that a depository must submit to the USPTO when seeking recognition by the Office as a suitable depository under 37 CFR 1.803(a)(2). This information enables the USPTO to evaluate whether such a depository has internal practices (both technical and administrative) and the technical ability sufficient to protect the integrity of the biological materials being stored by U.S. patent applicants. This information includes:

- (1) The name and address of the depository seeking recognition under 37 CFR 1.803(a)(2),
- (2) Detailed information as to the capacity of the depository to comply with the requirements of 37 CFR 1.803(a)(2), including information on its legal status, scientific standing, staff, and facilities;
- (3) An indication that the depository intends to be available, for the purposes of deposit, to any depositor under these same conditions;
- (4) Where the depository intends to accept for deposit only certain kinds of biological material, specify such kinds; and
- (5) An indication of the amount of any fees that the depository will, upon acquiring the status of suitable depository under paragraph (a)(2) of this section, charge for storage, viability statements and furnishings of samples of the deposit.

This collection also includes additional information gathered by the

USPTO that may be needed after a depository has been recognized by the USPTO under 37 CFR 1.803(a)(2), such as requests to handle additional types of biological materials other than the material originally recognized, and viability statements that depositories may submit on behalf of depositors for deposits tested at the depository and/or documentation proving the public has been notified about where to obtain samples. There is no application form associated with requests under 37 CFR 1.803(b) to become a recognized depository.

II. Method of Collection

Electronically via the USPTO's patent electronic filing system, by mail or hand delivery to the USPTO.

III. Data

OMB Control Number: 0651–0022.

Forms: No form associated for domestic depositories; Forms BP/1, BP/2, BP/3, BP/9 for use of international depositories under the Budapest Treaty.

- BP/1 (Statement in the Case of an Original Deposit (Rule 6.1))
- BP/2 (Statement in the Case of a New Deposit with the Same International Depository Authority (Rule 6.2))
- BP/3 (Statement in the Case of a New Deposit with Another International Depository Authority (Rule 6.2))
- BP/9 (Viability Statement (Rule 10.2) (International Form))

Type of Review: Extension and revision of a currently approved information collection.

Affected Public: Private sector.

Respondent's Obligation: Required to obtain or retain benefits.

Estimated Number of Annual Respondents: 3,301 respondents.

Estimated Number of Annual Responses: 3,301 responses.

Estimated Time per Response: The USPTO estimates that the responses in this information collection will take the public approximately between 1 hour and 5 hours to complete, depending on the complexity of the situation and item, to gather the necessary information, prepare the appropriate document(s), and submit the information to the USPTO.

Estimated Total Annual Respondent Burden Hours: 3,305 hours.

Estimated Total Annual Respondent Hourly Cost Burden: \$475,788.

TABLE 1—TOTAL BURDEN HOURS AND HOURLY COSTS TO PRIVATE SECTOR RESPONDENTS

Item No.	Item	Estimated annual respondents	Responses per respondent	Estimated annual responses	Estimated time per response (hours)	Estimated burden (hour/year)	Rate ¹ (\$/hour)	Estimated annual respondent cost burden
		(a)	(b)	(a) × (b) = (c)	(d)	(c) × (d) = (e)	(f)	(e) × (f) = (g)
1	Deposited Materials	3,300	1	3,300	1	3,300	\$143.96	\$475,068
2	Request for Depository Approval	1	1	1	5	5	143.96	720
	Totals	3,301		3,301		3,305		475,788

¹ Bureau of Labor Statistic rate for attorneys in scientific research and development services (23-1011—Lawyers), plus 30% added for benefits and overhead (<https://www.bls.gov/oes/current/oes231011.htm>).

Estimated Total Annual Respondent Non-hourly Cost Burden: \$9,259,809.

There are no maintenance costs, record keeping costs, or filing fees associated with this information collection. However, the USPTO estimates that the total annual (non-hour) cost burden for this information collection, in the form of capital start-up costs (\$8,250,000) and postage (\$1,009,809) is \$9,259,809.

Capital Start-Up Costs

Depositories charge fees to depositors; all depositories charge about the same rates for their services. For example, the American Type Culture Collection (ATCC), one of the world's leading biological supply houses and recognized patent depositories, offers comprehensive patent services for \$2,500 per deposit. Any deposits from outside the US may have additional requirements, from other Federal Agencies, as a part of their importation process. The USPTO estimates that the total non-hour respondent cost burden in the form of capital start-up costs amounts to \$8,250,000 (3,300 respondents × \$2,500).

Postage

Biological deposits are generally shipped to the depository "Domestic Overnight" by Federal Express (FedEx) and, since depositors are urged to supply frozen or freeze-dried material, it must be packed in dry ice. Dry ice itself is considered dangerous goods and requires special packaging. Additional FedEx special handling charges for inaccessible dangerous goods shipments of \$40 per shipment apply for temperature-sensitive biological materials and also for the dry ice. An average cost for shipping by FedEx "Domestic Overnight" is estimated to be \$90. If the shipment requires a pick-up by FedEx, there is an additional charge of \$6. Special packaging is also required for these shipments. The average cost of frozen infectious shippers is estimated to be \$170 per package of four for specimen shipments requiring refrigeration or dry ice. Therefore, the USPTO estimates the total postage costs

average \$306 per shipment, for a cost to respondents of \$1,009,800 (3,300 respondents × \$306).

The USPTO estimates that it will receive from depositories 1 request for recognition. The USPTO estimates that the postage cost for a mailed submission of a request for recognition from a depository using a Priority Mail 2-day flat rate legal envelope is \$9.25. Therefore, the USPTO estimates that the total mailing costs for this information collection is \$9.00 per year.

IV. Request for Comments

The USPTO is soliciting public comments to:

(a) Evaluate whether the collection of information is necessary for the proper performance of the functions of the Agency, including whether the information will have practical utility;

(b) Evaluate the accuracy of the Agency's estimate of the burden of the collection of information, including the validity of the methodology and assumptions used;

(c) Enhance the quality, utility, and clarity of the information to be collected; and

(d) Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, e.g., permitting electronic submission of responses.

All comments submitted in response to this notice are a matter of public record. USPTO will include or summarize each comment in the request to OMB to approve this information collection. Before including an address, phone number, email address, or other personally identifiable information (PII) in a comment, be aware that the entire comment—including PII—may be made publicly available at any time. While you may ask in your comment to withhold PII from public view, USPTO

cannot guarantee that it will be able to do so.

Justin Isaac,

Information Collections Officer, Office of the Chief Administrative Officer, United States Patent and Trademark Office.

[FR Doc. 2022-25364 Filed 11-21-22; 8:45 am]

BILLING CODE 3510-16-P

DEPARTMENT OF COMMERCE

Patent and Trademark Office

Agency Information Collection Activities; Submission to the Office of Management and Budget (OMB) for Review and Approval; Comment Request; Legal Processes

The United States Patent and Trademark Office (USPTO) will submit the following information collection request to the Office of Management and Budget (OMB) for review and clearance in accordance with the Paperwork Reduction Act of 1995, on or after the date of publication of this notice. The USPTO invites comment on this information collection renewal, which helps the USPTO assess the impact of its information collection requirements and minimize the public's reporting burden. Public comments were previously requested via the **Federal Register** on September 16, 2022 during a 60-day comment period. This notice allows for an additional 30 days for public comments.

Agency: United States Patent and Trademark Office, Department of Commerce.

Title: Legal Processes.

OMB Control Number: 0651-0046.

Needs and Uses: This collection covers information requirements related to civil actions and claims involving current and former employees of the United States Patent and Trademark Office (USPTO). The rules for these legal processes may be found under 37 CFR part 104, which outlines procedures for service of process, demands for employee testimony and production of documents in legal

proceedings, reports of unauthorized testimony, employee indemnification, and filing claims against the USPTO under the Federal Tort Claims Act (28 U.S.C. 2672) and the corresponding Department of Justice regulations (28 CFR part 14). The public may also petition the USPTO Office of General Counsel under 37 CFR 104.3 to waive or suspend these rules in extraordinary cases.

The procedures under 37 CFR part 104 ensure that service of process intended for current and former employees of the USPTO is handled properly. The USPTO will only accept service of process for an employee acting in an official capacity. This collection is necessary so that respondents or their representatives can serve a summons or complaint on the USPTO, demand employee testimony and documents related to a legal proceeding, or file a claim under the Federal Tort Claims Act. Respondents may also petition the USPTO to waive or suspend these rules for legal processes. This collection is also necessary so that current and former USPTO employees may properly forward service and demands to the Office of General Counsel, report unauthorized testimony, and request indemnification. The USPTO covers current employees as respondents under this information collection even though their responses do not require approval under the Paperwork Reduction Act. In those instances where both current and former employees may respond to the USPTO, the agency estimates that the number of respondents will be small.

There are no forms provided by the USPTO for this collection. For filing claims under the Federal Tort Claims Act, the public may use Standard Form 95 "Claim for Damage, Injury, or Death," which is provided by the Department of Justice and approved by OMB under OMB Control Number 1105-0008.

Form Number(s):

- Standard Form 95 (Claim for Damage, Injury, or Death).

Type of Review: Extension and revision of a currently approved information collection.

Affected Public: Private sector; individuals or households.

Respondent's Obligation: Required to obtain or retain benefits.

Frequency: On occasion.

Estimated Number of Annual Respondents: 309 respondents.

Estimated Number of Annual Responses: 309 responses.

Estimated Time per Response: The USPTO estimates that the responses in this information collection will take the

public between approximately 5 minutes (0.08 hours) and 6 hours to complete. This includes the time to gather the necessary information, create the document, and submit the completed request to the USPTO.

Estimated Total Annual Respondent Burden Hours: 133 hours.

Estimated Total Annual Respondent Non-Hourly Cost Burden: \$4,569.

This information collection request may be viewed at www.reginfo.gov. Follow the instructions to view Department of Commerce, USPTO information collections currently under review by OMB.

Written comments and recommendations for this information collection should be submitted within 30 days of the publication of this notice on the following website www.reginfo.gov/public/do/PRAMain. Find this particular information collection by selecting "Currently under 30-day Review—Open for Public Comments" or by using the search function and entering either the title of the information collection or the OMB Control Number 0651-0046.

Further information can be obtained by:

- *Email:* InformationCollection@uspto.gov. Include "0651-0046 information request" in the subject line of the message.

- *Mail:* Justin Isaac, Office of the Chief Administrative Officer, United States Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313-1450.

Justin Isaac,

Information Collections Officer, Office of the Chief Administrative Officer, United States Patent and Trademark Office.

[FR Doc. 2022-25381 Filed 11-21-22; 8:45 am]

BILLING CODE 3510-16-P

DEPARTMENT OF COMMERCE

United States Patent and Trademark Office

Agency Information Collection Activities; Submission to the Office of Management and Budget (OMB) for Review and Approval; Comment Request; Post Allowance and Reissue

AGENCY: United States Patent and Trademark Office, Department of Commerce.

ACTION: Notice of information collection; request for comment.

SUMMARY: The United States Patent and Trademark Office (USPTO), as required by the Paperwork Reduction Act of 1995, invites comments on the

extension and revision of an existing information collection: 0651-0033 Post Allowance and Reissue. The purpose of this notice is to allow 60 days for public comment preceding submission of the information collection to OMB.

DATES: To ensure consideration, comments regarding this information collection must be received on or before February 21, 2023.

ADDRESSES: Interested persons are invited to submit written comments by any of the following methods. Do not submit Confidential Business Information or otherwise sensitive or protected information.

- *Email:* InformationCollection@uspto.gov. Include "0651-0033 comment" in the subject line of the message.

- *Federal Rulemaking Portal:* <http://www.regulations.gov>.

- *Mail:* Justin Isaac, Office of the Chief Administrative Officer, United States Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313-1450.

FOR FURTHER INFORMATION CONTACT:

Requests for additional information should be directed to Parikha Mehta, Senior Legal Advisor, United States Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313-1450; by telephone at 571-272-3248; or by email at parikha.mehta@uspto.gov with "0651-0033 comment" in the subject line. Additional information about this information collection is also available at <http://www.reginfo.gov> under "Information Collection Review."

SUPPLEMENTARY INFORMATION:

I. Abstract

This collection of information covers the submission of issue fee payments, requests for certificates of correction, and reissue applications to the United States Patent and Trademark Office (USPTO). The USPTO is required by 35 U.S.C. 131 and 151 to examine applications and, when appropriate, allow applications and issue them as patents. When an application for a patent is allowed by the USPTO, the USPTO issues a notice of allowance and the applicant must pay the specified issue fee within three months to avoid abandonment of the application. If the appropriate fees are paid within the proper time period, the USPTO can then issue the patent. The rules outlining the procedures for payment of the issue fee and issuance of a patent are found at 37 CFR 1.18, 1.311, and 1.314.

This collection of information also covers several transactions that may be taken after issuance of a patent.

Pursuant to 35 U.S.C. 254 and 255, a certificate of correction may be requested to correct an error or errors in an issued patent. If the USPTO determines that the request should be approved, the USPTO will issue a certificate of correction.

For an original patent that is believed to be wholly or partly inoperative or invalid, the original patentee, or the current patent owner if there has been a subsequent assignment, may apply for reissue of the patent. The reissue application process requires, among other items, provision of an oath or declaration specifically identifying at least one error being relied upon as the basis for reissue and stating the reason for the belief that the original patent is wholly or partly inoperative or invalid (e.g., a defective specification or drawing, or claiming more or less than the patentee had the right to claim in the patent). The rules outlining reissue application procedures are found at 37 CFR 1.171–1.173 and 1.175–1.178.

The title of this item has been changed from “Post Allowance and Refiling” to “Post Allowance and

Reissue” to better reflect the nature of the items in this information collection.

II. Method of Collection

Electronically via the USPTO’s patent electronic filing system, by mail, or by hand delivery to the USPTO.

III. Data

OMB Control Number: 0651–0033.

Forms: (AIA = America Invents Act; SB = Specimen Book; PTOL = Patent Trademark Office Legal Form).

- PTO/AIA/05, PTO/AIA/06, PTO/SB/51, PTO/SB/52 (Reissue Application Declaration by the Inventor or the Assignee)
- PTO/AIA/07 (Substitute Statement in Lieu of an Oath or Declaration for Reissue Patent Application (35 U.S.C. 115(d) and 37 CFR 1.64)
- PTO/AIA/50 (Reissue Patent Application Transmittal)
- PTO/AIA/53, PTO/SB/53 (Reissue Application: Consent of Assignee; Statement of Non-Assignment)
- PTO/SB/44 (Certificate of Correction)
- PTO/SB/51S, (Supplemental Declaration for Reissue Patent

Application to Correct “Errors” Statement (pre-AIA 37 CFR 1.175(c))

- PTO/SB/56 (Reissue Application Fee Transmittal Form)
- PTOL–85B (Issue Fee Transmittal)

Type of Review: Extension and revision of a currently approved information collection.

Affected Public: Private sector; individuals or households.

Respondent’s Obligation: Required to obtain or retain benefits.

Estimated Number of Annual Respondents: 426,301 respondents.

Estimated Number of Annual Responses: 426,301 responses.

Estimated Time per Response: The USPTO estimates that the responses in this information collection will take the public approximately between 30 minutes (0.5 hours) and 5.3 hours to complete. This includes the time to gather the necessary information, create the document, and submit the completed item to the USPTO.

Estimated Total Annual Respondent Burden Hours: 373,568 hours.

Estimated Total Annual Respondent Hourly Cost Burden: \$162,502,080.

TABLE 1—TOTAL BURDEN HOURS AND HOURLY COSTS TO PRIVATE SECTOR RESPONDENTS

Item No.	Item	Estimated annual respondents	Responses per respondent	Estimated annual responses	Estimated time per response (hour)	Estimated burden (hour/year)	Hourly cost burden rate ¹	Total annual cost for time spent
		(a)	(b)	(a) × (b) = (c)	(d)	(c) × (d) = (e)	(f)	(e) × (f) = (g)
1	Certificate of Correction (PTO/SB/44)	58,200	1	58,200	1.3 (80 minutes) ..	75,660	\$435	\$32,912,100
2	Petition to Correct Assignee After Payment of Issue Fee (37 CFR 3.81(b)).	534	1	534	0.8 (46 minutes) ..	427	435	185,745
3	Reissue Documentation	698	1	698	5.3 (318 minutes)	3,699	435	1,609,065
4	Reissue Patent Application Transmittal.	698	1	698	0.5 (30 minutes) ..	349	435	151,815
5	(PTO/SB/50)							
5	Reissue Application Declaration by the Inventor or the Assignee (PTO/SB/51/52, PTO/AIA/05/06) or Substitute Statement in Lieu of an Oath or Declaration for Reissue Patent Application (35 U.S.C. 115(d) and 37 CFR 1.64) (PTO/AIA/07).	1,175	1	1,175	0.8 (46 minutes) ..	940	435	408,900
6	Supplemental Declaration for Reissue Patent Application to Correct “Errors” Statement (37 CFR 1.175) (PTO/SB/51S).	30	1	30	0.6 (36 minutes) ..	18	435	7,830
7	Reissue Application: Consent of Assignee; Statement of Non-assignment (PTO/SB/53, PTO/AIA/53).	889	1	889	0.5 (30 minutes) ..	445	435	193,575
8	Reissue Application Fee Transmittal Form (PTO/SB/56).	698	1	698	0.5 (30 minutes) ..	349	435	151,815
9	Issue Fee Transmittal (PTOL–85B) ...	350,588	1	350,588	0.8 (46 minutes) ..	280,470	435	122,004,450
	Totals	413,510	413,510	362,357	157,625,295

¹ 2021 Report of the Economic Survey, published by the Committee on Economics of Legal Practice of the American Intellectual Property Law Association (AIPLA); pg. F–27. The USPTO uses the average billing rate for intellectual property attorneys in private firms which is \$435 per hour.

TABLE 2—TOTAL BURDEN HOURS AND HOURLY COSTS TO INDIVIDUAL AND HOUSEHOLD RESPONDENTS

Item No.	Item	Estimated annual respondents	Responses per respondent	Estimated annual responses	Estimated time per response (hour)	Estimated burden (hour/year)	Hourly cost burden rate ²	Total annual cost for time Spent
		(a)	(b)	(a) × (b) = (c)	(d)	(c) × (d) = (e)	(f)	(e) × (f) = (g)
1	Certificate of Correction (PTO/SB/44)	1,800	1	1,800	1.3 (80 minutes) ..	2,340	\$435	\$1,017,900
2	Petition to Correct Assignee After Payment of Issue Fee (37 CFR 3.81(b)).	16	1	16	0.8 (46 minutes) ..	13	435	5,655
3	Reissue Documentation	22	1	22	5.3 (320 minutes)	117	435	50,895
4	Reissue Patent Application Transmittal (PTO/SB/50).	22	1	22	0.5 (30 minutes) ..	11	435	4,785
5	Reissue Application Declaration by the Inventor or the Assignee (PTO/SB/51/52, PTO/AIA/05/06) or Substitute Statement in Lieu of an Oath or Declaration for Reissue Patent Application (35 U.S.C. 115(d) and 37 CFR 1.64) (PTO/AIA/07).	37	1	37	0.8 (46 minutes) ..	30	435	13,050
6	Supplemental Declaration for Reissue Patent Application to Correct "Errors" Statement (37 CFR 1.175) (PTO/SB/51S).	1	1	1	0.6	1	435	435
7	Reissue Application: Consent of Assignee; Statement of Non-assignment (PTO/SB/53, PTO/AIA/53).	28	1	28	0.5	14	435	6,090
8	Reissue Application Fee Transmittal Form (PTO/SB/56).	22	1	22	0.5	11	435	4,785
9	Issue Fee Transmittal (PTOL-85B) ...	10,843	1	10,843	0.8 (46 minutes) ..	8,674	435	3,773,190
	Totals	12,791	12,791	11,211	4,876,785

² Ibid.

Estimated Total Annual Respondent Non-hourly Cost Burden: \$434,518,228.

There are no maintenance costs, capital start-up costs, or recordkeeping costs associated with this information collection. However, the USPTO

estimates that the total annual (nonhour) cost burden for this information collection, in the form of filing fees (\$434,478,795) and postage (\$39,433), is \$434,518,228.

Filing Fees

The items with filing fees are listed in the table below.

TABLE 3—FILING FEES

Item No.	Type of cost	Estimated annual responses	Amount	Totals
1	Certificate of correction (Undiscounted entity)	9,521	\$160	\$1,523,360
1	Certificate of correction (Small entity)	2,394	160	383,040
1	Certificate of correction (Micro entity)	90	160	14,400
3	Basic filing fee—Reissue (Undiscounted entity)	1,501	320	480,320
3	Basic filing fee—Reissue (Small entity)	528	160	84,480
3	Basic filing fee—Reissue (Micro entity)	65	80	5,200
3	Basic Filing Fee—Reissue (Design CPA) (Undiscounted entity)	25	320	8,000
3	Basic Filing Fee—Reissue (Design CPA) (Small entity)	5	160	800
3	Basic Filing Fee—Reissue (Design CPA) (Micro entity)	5	80	400
3	Reissue Search Fee or Reissue Design CPA Search Fees (Undiscounted entity).	1,544	700	1,080,800
3	Reissue Search Fee or Reissue Design CPA Search Fees (Small entity)	580	350	203,000
3	Reissue Search Fee or Reissue Design CPA Search Fees (Micro entity)	72	175	12,600
3	Reissue independent claims in excess of three (Undiscounted entity)	561	480	269,280
3	Reissue independent claims in excess of three (Small entity)	176	240	42,240
3	Reissue independent claims in excess of three (Micro entity)	21	120	2,520
3	Reissue claims in excess of 20 (Undiscounted entity)	4,531	100	453,100
3	Reissue claims in excess of 20 (Small entity)	1,495	50	74,750
3	Reissue claims in excess of 20 (Micro entity)	115	25	2,875
3, 4	Reissue Application Size Fee—for each additional 50 sheets that exceeds 100 sheets (Undiscounted entity).	46	420	19,320
3, 4	Reissue Application Size Fee—for each additional 50 sheets that exceeds 100 sheets (Small entity).	10	210	2,100
3, 4	Reissue Application Size Fee—for each additional 50 sheets that exceeds 100 sheets (Micro entity).	8	105	840
3	Reissue Examination Fee or Reissue Design CPA Examination Fee (Undiscounted entity).	1,542	2,320	3,577,440

TABLE 3—FILING FEES—Continued

Item No.	Type of cost	Estimated annual responses	Amount	Totals
3	Reissue Examination Fee or Reissue Design CPA Examination Fee (Small entity)	577	1,160	669,320
3	Reissue Examination Fee or Reissue Design CPA Examination Fee (Micro entity)	70	580	40,600
9	Utility issue fee (Undiscounted entity)	294,254	1,200	353,104,800
9	Utility issue fee (Small entity)	79,574	600	47,744,400
9	Utility issue fee (Micro entity)	9,678	300	2,903,400
9	Design issue fee (Undiscounted entity)	18,674	740	13,818,760
9	Design issue fee (Small entity)	14,600	370	5,402,000
9	Design issue fee (Micro entity)	6,228	185	1,152,180
9	Plant issue fee (Undiscounted entity)	641	840	538,440
9	Plant issue fee (Small entity)	598	420	251,160
9	Plant issue fee (Micro entity)	7	210	1,470
9	Reissue issue fee (Undiscounted entity)	448	1,200	537,600
9	Reissue issue fee (Small entity)	120	600	72,000
9	Reissue issue fee (Micro entity)	6	300	1,800
	Total Filing Fees	450,310	434,478,795

Postage

Although the USPTO prefers that the items in this information collection be submitted electronically, responses may be submitted by mail through the United States Postal Service (USPS). Customers may incur postage costs when submitting the information in this information collection to the USPTO by mail. The USPTO expects that approximately 1% (4,263) of the responses for this information collection will be submitted by mail. The USPTO estimates that the average postage cost for a mailed submission, using a Priority Mail 2-day flat rate legal envelope, will be \$9.25 and that approximately 4,263 submissions will be mailed to the USPTO per year. Therefore, the USPTO estimates that postage costs in this collection will be \$39,433.

IV. Request for Comments

The USPTO is soliciting public comments to:

(a) Evaluate whether the collection of information is necessary for the proper performance of the functions of the Agency, including whether the information will have practical utility;

(b) Evaluate the accuracy of the Agency's estimate of the burden of the collection of information, including the validity of the methodology and assumptions used;

(c) Enhance the quality, utility, and clarity of the information to be collected; and

(d) Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or

other forms of information technology, *e.g.*, permitting electronic submission of responses.

All comments submitted in response to this notice are a matter of public record. USPTO will include or summarize each comment in the request to OMB to approve this information collection. Before including an address, phone number, email address, or other personally identifiable information (PII) in a comment, be aware that the entire comment—including PII—may be made publicly available at any time. While you may ask in your comment to withhold PII from public view, USPTO cannot guarantee that it will be able to do so.

Justin Isaac,

Information Collections Officer, Office of the Chief Administrative Officer, United States Patent and Trademark Office.

[FR Doc. 2022–25362 Filed 11–21–22; 8:45 am]

BILLING CODE 3510–16–P

BUREAU OF CONSUMER FINANCIAL PROTECTION

[Docket No. CFPB–2022–0076]

Agency Information Collection Activities: Comment Request

AGENCY: Bureau of Consumer Financial Protection.

ACTION: Notice and request for comment.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995 (PRA), the Consumer Financial Protection Bureau (Bureau or CFPB) requests the extension of the Office of Management and Budget's (OMB's) approval of the existing information

collection titled “Disclosure Requirements for Depository Institutions Lacking Federal Deposit Insurance (Regulation I)” approved under OMB Number 3170–0062.

DATES: Written comments are encouraged and must be received on or before December 22, 2022 to be assured of consideration.

ADDRESSES: Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to www.reginfo.gov/public/do/PRAMain. Find this particular information collection by selecting “Currently under 30-day Review—Open for Public Comments” or by using the search function. In general, all comments received will become public records, including any personal information provided. Sensitive personal information, such as account numbers or Social Security numbers, should not be included.

FOR FURTHER INFORMATION CONTACT: Documentation prepared in support of this information collection request is available at www.regulations.gov. Requests for additional information should be directed to Anthony May, Paperwork Reduction Act Officer, at (202) 435–7278, or email: CFPB_PRA@cfpb.gov. If you require this document in an alternative electronic format, please contact CFPB_Accessibility@cfpb.gov. Please do not submit comments to these email boxes.

SUPPLEMENTARY INFORMATION:

Title of Collection: Disclosure Requirements for Depository Institutions Lacking Federal Deposit Insurance (Regulation I).

OMB Control Number: 3170–0062.

Type of Review: Extension without change of a currently approved collection.

Affected Public: Private sector: businesses or other for-profits; not-for-profits institutions.

Estimated Number of Respondents: 167.

Estimated Total Annual Burden Hours: 4,609.

Abstract: Regulation I, 12 CFR part 1009, applies to all depository institutions lacking Federal deposit insurance. It requires the disclosure of certain insurance-related information in periodic statements, account records, locations where deposits are normally received, and advertising. This part also requires such depository institutions to obtain a written acknowledgment from depositors regarding the institution's lack of Federal deposit insurance. This is a routine request for OMB to renew its approval of the collections of information currently approved under this OMB control number. The Bureau is not proposing any new or revised collections of information pursuant to this request.

Request for Comments: The Bureau published a 60-day **Federal Register** notice on September 9, 2022 (87 FR 55412) under Docket Number: CFPB–2022–0060. The Bureau is publishing this notice and soliciting comments on: (a) Whether the collection of information is necessary for the proper performance of the functions of the Bureau, including whether the information will have practical utility; (b) The accuracy of the Bureau's estimate of the burden of the collection of information, including the validity of the methods and the assumptions used; (c) Ways to enhance the quality, utility, and clarity of the information to be collected; and (d) Ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology. Comments submitted in response to this notice will be reviewed by OMB as part of its review of this request. All comments will become a matter of public record.

Anthony May,

Paperwork Reduction Act Officer, Consumer Financial Protection Bureau.

[FR Doc. 2022–25373 Filed 11–21–22; 8:45 am]

BILLING CODE 4810–AM–P

BUREAU OF CONSUMER FINANCIAL PROTECTION

[Docket No. CFPB–2022–0077]

Agency Information Collection Activities: Comment Request

AGENCY: Bureau of Consumer Financial Protection.

ACTION: Notice and request for comment.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995 (PRA), the Consumer Financial Protection Bureau (Bureau or CFPB) requests the extension of the Office of Management and Budget's (OMB's) approval of the existing information collection titled “Home Mortgage Disclosure Act (Regulation C)” approved under OMB Number 3170–0008.

DATES: Written comments are encouraged and must be received on or before December 22, 2022 to be assured of consideration.

ADDRESSES: Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to www.reginfo.gov/public/do/PRAMain. Find this particular information collection by selecting “Currently under 30-day Review—Open for Public Comments” or by using the search function.

In general, all comments received will become public records, including any personal information provided. Sensitive personal information, such as account numbers or Social Security numbers, should not be included.

FOR FURTHER INFORMATION CONTACT: Documentation prepared in support of this information collection request is available at www.regulations.gov. Requests for additional information should be directed to Anthony May, Paperwork Reduction Act Officer, at (202) 435–7278, or email: CFPB_PRA@cfpb.gov. If you require this document in an alternative electronic format, please contact CFPB_Accessibility@cfpb.gov. Please do not submit comments to these email boxes.

SUPPLEMENTARY INFORMATION:

Title of Collection: Home Mortgage Disclosure Act (Regulation C).

OMB Control Number: 3170–0008.

Type of Review: Extension without change of a currently approved collection.

Affected Public: Individuals and households.

Estimated Number of Respondents: 136.

Estimated Total Annual Burden Hours: 1,472,000.

Abstract: The Home Mortgage Disclosure Act (HMDA) requires certain depository institutions and for-profit, non-depository institutions to collect, report, and disclose data about originations and purchases of mortgage loans. Additionally, these institutions must report mortgage loan applications that do not result in originations (for example, applications that are denied or withdrawn). The Bureau's Regulation C (12 CFR part 1003) implements HMDA. The purpose of the information collection is:

- To help determine whether financial institutions are serving the housing needs of their communities;
- To assist public officials in distributing public-sector investment so as to attract private investment to areas where it is needed; and
- To assist in identifying possible discriminatory lending patterns and enforcing antidiscrimination statutes.

The information collection will also assist the Bureau's examiners (and examiners of other Federal supervisory agencies) in determining whether the financial institutions they supervise comply with applicable provisions of HMDA.

Request for Comments: The Bureau published a 60-day **Federal Register** notice on September 19, 2022 (87 FR 57181) under Docket Number: CFPB–2022–0063. The Bureau is publishing this notice and soliciting comments on: (a) Whether the collection of information is necessary for the proper performance of the functions of the Bureau, including whether the information will have practical utility; (b) The accuracy of the Bureau's estimate of the burden of the collection of information, including the validity of the methods and the assumptions used; (c) Ways to enhance the quality, utility, and clarity of the information to be collected; and (d) Ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology. Comments submitted in response to this notice will be reviewed by OMB as part of its review of this request. All comments will become a matter of public record.

Anthony May,

Paperwork Reduction Act Officer, Consumer Financial Protection Bureau.

[FR Doc. 2022–25411 Filed 11–21–22; 8:45 am]

BILLING CODE 4810–AM–P

DEPARTMENT OF DEFENSE**Office of the Secretary****Defense Business Board; Notice of Change to Federal Advisory Committee Meeting Agenda**

AGENCY: Office of the Deputy Secretary of Defense, Department of Defense (DoD).

ACTION: Notice of change to Federal Advisory Committee meeting agenda.

SUMMARY: The DoD is publishing this notice to announce changes to the agenda of the November 9–10, 2022 meeting of the Defense Business Board (“the Board”), which was previously published on October 13, 2022.

DATES: Closed to the public Wednesday, November 9, 2022 from 11:10 a.m. to 12:05 p.m., 3:25 p.m. to 5:05 p.m., and from 5:30 p.m. to 7:35 p.m. Open to the public Thursday, November 10, 2022 from 8:30 a.m. to 12:35 p.m. All eastern time.

ADDRESSES: The open and closed portions of the meeting were in the Joint Staff Conference Center Room 1E840 and Air Force Mess Room 4D880 in the Pentagon, Washington, DC. As previously stated, participation in the open portion of meetings, see the Meeting Accessibility section for instructions.

FOR FURTHER INFORMATION CONTACT: Ms. Jennifer Hill, Designated Federal Officer (DFO) of the Board in writing at Defense Business Board, 1155 Defense Pentagon, Room 5B1088A, Washington, DC 20301–1155; or by email at jennifer.s.hill4.civ@mail.mil; or by phone at 571–342–0070.

SUPPLEMENTARY INFORMATION: This meeting was held under the provisions of the Federal Advisory Committee Act (FACA) (5 U.S.C. Appendix), the Government in the Sunshine Act (5 U.S.C. 552b), and 41 CFR 102–3.140 and 102–3.150.

Due to circumstances beyond the control of the Designated Federal Officer, the Defense Business Board was unable to provide the public notification required by 41 CFR 102–3.150(a) to announce changes to its November 9–10, 2022 meeting agenda that was previously published on October 13, 2022. See 87 FR 62084–62085. Accordingly, the Advisory Committee Management Officer for the Department of Defense, pursuant to 41 CFR 102–3.150(b), waives the 15-calendar day notification requirement.

Purpose of the Meeting: The mission of the Board is to examine and advise the Secretary of Defense on overall DoD

management and governance. The Board provides independent, strategic-level, private sector and academic advice and counsel on enterprise-wide business management approaches and best practices for business operations and achieving National Defense goals.

Agenda: The amended agenda has the Board beginning in closed session on November 9, 2022 from 11:10 a.m. to 12:05 p.m. with opening remarks by Ms. Jennifer Hill, the DFO. The Board received a classified brief on the resiliency of the Defense Industrial Base from the Honorable Kathleen Hicks, Deputy Secretary of Defense, and the Honorable Deborah G. Rosenblum, Performing the Duties of the Assistant Secretary of Defense for Industrial Base Policy. The DFO then adjourned the closed session. The Board reconvened in closed session on November 9, 2022 at 3:25 p.m. to 5:05 p.m. Next, the Board received a classified update on DoD Events by the Honorable Lloyd J. Austin III, Secretary of Defense, followed by a classified discussion on streamlining DoD intelligence processes by the Honorable Ronald S. Moultrie, Under Secretary of Defense for Intelligence & Security. The DFO then adjourned the closed session. The Board met in closed session on November 9, 2022 from 5:30 p.m. to 7:35 p.m. The DFO opened the closed session followed by the Chair’s remarks, and remarks from Deputy Secretary of Defense Hicks. The Board received a classified discussion by the Honorable Heidi Shyu, Under Secretary of Defense for Research and Engineering, on how the Department is preparing for future conflicts. The DFO adjourned the closed session. The Board began in an open session on November 10, 2022 at 8:30 a.m. with opening remarks by the DFO and Chair’s welcome to members and guests. Next, the Board received a presentation and then deliberated and voted on the Board’s “Recommendations to Improve Department of Defense Business Health Metrics” study led by Ms. Erin Hill, Chair, Business Transformation Advisory Subcommittee. The Board then received an update on DoD civilian training by the Honorable Gilbert Cisneros, Under Secretary of Defense for Personnel and Readiness, and Mr. Tom Constable, Acting Assistant Secretary of Defense, Manpower and Reserve Affairs. The Honorable Michael B. Donley, Director, Administration and Management, presented a follow-up brief on the dissolution of the Office of the Chief Management Officer and current business improvement efforts. Closing remarks by the Chair and the DFO adjourned the open session. The

latest version of the agenda is available on the Board’s website: <https://dbb.defense.gov/Meetings/Meeting-November-2022/>.

Meeting Accessibility: In accordance with Section 10(d) of the FACA and 41 CFR 102–3.155, and as previously published on October 13, 2022, it was determined that portions of the November 9–10, 2022 meeting of the Board included classified information and other matters covered by 5 U.S.C. 552b(c)(1) and that, accordingly, the meeting was closed to the public on November 9, 2022 from 11:10 a.m. to 12:05 p.m., from 3:25 p.m. to 5:05 p.m. and from 5:30 p.m. to 7:35 p.m. This determination was based on the consideration that it is expected that discussions throughout these periods will involve classified matters of national security. Such classified material is so intertwined with the unclassified material that it cannot reasonably be segregated into separate discussions without defeating the effectiveness and meaning of these portions of the meeting. To permit these portions of the meeting to be open to the public would have precluded discussion of such matters and would greatly diminish the ultimate utility of the Board’s findings and recommendations to the Secretary of Defense and to the Deputy Secretary of Defense. Pursuant to section 10(a)(1) of the FACA and 41 CFR 102–3.140, the portion of the meeting on November 10, 2022 from 8:30 a.m. to 12:35 p.m. was open to the public. As previously published and announced, persons that desired to attend the public session were required to register and submit your name, affiliation/organization, telephone number, and email contact information to the Board at osd.pentagon.odam.mbx.defense-business-board@mail.mil.

Written Comments and Statements: Pursuant to 41 CFR 102–3.105(j) and 102–3.140 and section 10(a)(3) of the FACA, the public or interested organizations may submit written comments or statements to the Board in response to the stated agenda of the meeting or regarding the Board’s mission in general. Written comments or statements should be submitted to Ms. Jennifer Hill, the DFO, via electronic mail at the address listed in the **FOR FURTHER INFORMATION CONTACT** section. Each page of the comment or statement must include the author’s name, title or affiliation, address, and daytime phone number. The DFO must have received all written comments or statements submitted in response to the agenda set forth in this notice by Wednesday, November 2, 2022 to be

considered by the Board. Written comments or statements received after this date may not be provided to the Board until its next scheduled meeting. Please note that all submitted comments and statements will be treated as public documents and will be made available for public inspection, including, but not limited to, being posted on the Board's website.

Dated: November 17, 2022.

Aaron T. Siegel,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

[FR Doc. 2022-25442 Filed 11-21-22; 8:45 am]

BILLING CODE 5001-06-P

DEPARTMENT OF DEFENSE

Office of the Secretary

TRICARE; Calendar Year (CY) 2023; TRICARE Prime and TRICARE Select Out-of-Pocket Expenses

AGENCY: Office of the Secretary, Department of Defense.

ACTION: Notice of CY 2023 TRICARE Prime and TRICARE Select out-of-pocket expenses.

SUMMARY: This notice provides the CY 2023 TRICARE Prime and TRICARE Select out-of-pocket expenses.

DATES: The CY 2023 rates contained in this notice are effective January 1, 2023.

ADDRESSES: Defense Health Agency (DHA), TRICARE Health Plan, 7700 Arlington Boulevard, Suite 5101, Falls Church, Virginia 22042-5101.

FOR FURTHER INFORMATION CONTACT: Debra Fisher, telephone (703) 275-6224.

SUPPLEMENTARY INFORMATION: The National Defense Authorization Acts for Fiscal Years 2012 and 2017 established rates for TRICARE beneficiary out-of-pocket expenses and how they may be increased by the annual cost of living adjustment (COLA) percentage used to increase military retired pay or via budget neutrality rules. The CY 2023 retiree COLA increase is 8.7%.

The DHA has updated the CY 2023 out-of-pocket expenses as follows:

CALENDAR YEAR 2023 TRICARE PRIME AND TRICARE SELECT OUT-OF-POCKET EXPENSES: ACTIVE DUTY FAMILY MEMBERS (ADFM) CATEGORY

[Page 1 of 1]

Out of pocket expense	Select Group A CY23	Select Group B CY23	Prime* Group A CY23	Prime* Group B CY23
Annual enrollment fee:				
<i>Individual</i>	\$0	\$0	\$0	\$0
<i>Family</i>	\$0	\$0	0	0
Annual deductible:				
<i>E1-E4, individual</i>	\$50	\$60	0	0
<i>E1-E4, family</i>	\$100	\$121	0	0
<i>E5 & above, individual</i>	\$150	\$182	0	0
<i>E5 & above, family</i>	\$300	\$365	0	0
Annual catastrophic cap	\$1,000	\$1,217	1,000	1,217
Preventive visit	\$0	\$0	0	0
Primary care	\$25 (IN) 20% (OON)	\$18 (IN) 20% (OON)	0	0
Specialty care	\$37 (IN) 20% (OON)	\$30 (IN) 20% (OON)	0	0
ER visit	\$103 (IN) 20% (OON)	\$48 (IN) 20% (OON)	0	0
Urgent care center visit	\$25 (IN) 20% (OON)	\$24 (IN) 20% (OON)	0	0
Ambulatory surgery	\$25 (IN or OON)	\$30 (IN) 20% (OON)	0	0
Ambulance, outpatient ground	\$75 (IN) 20% (OON)	\$18 (IN) 20% (OON)	0	0
Ambulance, outpatient air	20% (IN or OON)	20% (IN or OON)	0	0
Durable medical equipment	15% (IN) 20% (OON)	10% (IN) 20% (OON)	0	0
Inpatient admission	\$21.30 per day; \$25 min. per admission ..	\$73 per adm. (IN); 20% (OON)	0	0
Inpatient SNF/rehab facility	\$21.30 per day; \$25 min. per admission ..	\$30 per day (IN); \$60 per day (OON)	0	0

*When TRICARE Prime enrollees other than active duty service members self-refer to specialty or non-emergent inpatient care without a referral from a network provider and/or authorization from the regional contractor, the TRICARE Point of Service deductible and copayment applies in lieu of TRICARE Prime copayments.

CALENDAR YEAR 2023 TRICARE PRIME AND TRICARE SELECT OUT-OF-POCKET EXPENSES: RETIREE BENEFICIARY CATEGORY

[Page 1 of 2]

Out of pocket expense	Select Group A CY23	Select Group B CY23	Prime* Group A CY23	Prime* Group B CY23
Annual enrollment fee:				
<i>Individual</i>	\$171.96	\$547.92	\$351.96	\$426
<i>Family</i>	\$345	\$1,095.96	703.92	852
Annual deductible:				
<i>E1-E4, individual</i>	\$150	\$182 (IN); \$365 (OON)	0	0
<i>Family</i>	\$300	\$365 (IN); \$730 (OON)	0	0
Annual catastrophic cap	\$4,028	\$4,262	3,000	4,262
Preventive visit	\$0	\$0	0	0
Primary care	\$34 (IN) 25% (OON)	\$30 (IN) 25% (OON)	24	24
Specialty care	\$49 (IN) 25% (OON)	\$48 (IN) 25% (OON)	36	36
ER visit	\$138 (IN) 25% (OON)	\$97 (IN) 25% (OON)	73	73
Urgent care center visit	\$34 (IN) 25% (OON)	\$48 (IN) 25% (OON)	36	36
Ambulatory surgery	20% (IN) 25% (OON)	\$115 (IN) 25% (OON)	73	73
Ambulance, outpatient ground	\$100 (IN) 25% (OON)	\$73 (IN) 25% (OON)	48	48
Ambulance, outpatient air	25% (IN or OON)	25% (IN or OON)	20	20

CALENDAR YEAR 2023 TRICARE PRIME AND TRICARE SELECT OUT-OF-POCKET EXPENSES: RETIREE BENEFICIARY CATEGORY
[Page 2 of 2]

Out of pocket expense	Select Group A CY23	Select Group B CY23	Prime * Group A CY23	Prime * Group B CY23
Durable medical equipment	20% (IN) 25% (OON)	20% (IN) 25% (OON)	20%	20%.
Inpatient admission:				
<i>In-network</i>	\$250/day up to 25% of hospital charges, plus 20% of sep. billed services.	\$213 per adm	\$182 per adm ..	\$182 per adm.
<i>Out of network</i>	‡ \$1,053/day up to 25% of hosp. charges, plus 25% of sep. billed services.	25%	\$182 per adm ..	\$182 per adm.
Inpatient SNF/rehab facility	\$250/day up to 25% of hospital charges, plus 20% of sep. billed services (IN); 25% (OON).	\$60 per day (IN); lesser of \$365 per day or 20% (OON).	\$36 per day	\$36 per day.

‡ This is the CY22 rate. The CY23 out of pocket expense will be available mid-December once the DRG payment rates are calculated.

* When TRICARE Prime enrollees other than active duty service members self-refer to specialty or non-emergent inpatient care without a referral from a network provider and/or authorization from the regional contractor, the TRICARE Point of Service deductible and copayment applies in lieu of TRICARE Prime copayments.

The CY 2023 rates contained in this notice are effective January 1, 2023.

Dated: November 17, 2022.

Aaron T. Siegel,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

[FR Doc. 2022-25439 Filed 11-21-22; 8:45 am]

BILLING CODE 5001-06-P

DEPARTMENT OF EDUCATION

[Docket No.: ED-2022-SCC-0145]

Agency Information Collection Activities; Submission to the Office of Management and Budget for Review and Approval; Comment Request; Application for Grants Under the Native American-Serving Nontribal Institutions Program ALN# 84.031X (1894-0001)

AGENCY: Office of Postsecondary Education (OPE), Department of Education (ED).

ACTION: Notice.

SUMMARY: In accordance with the Paperwork Reduction Act (PRA) of 1995, the Department is proposing an extension without change of a currently approved information collection request (ICR).

DATES: Interested persons are invited to submit comments on or before December 22, 2022.

ADDRESSES: Written comments and recommendations for proposed information collection requests should be submitted within 30 days of publication of this notice. Click on this link www.reginfo.gov/public/do/PRAMain to access the site. Find this information collection request (ICR) by selecting "Department of Education" under "Currently Under Review," then check the "Only Show ICR for Public Comment" checkbox. *Reginfo.gov* provides two links to view documents related to this information collection

request. Information collection forms and instructions may be found by clicking on the "View Information Collection (IC) List" link. Supporting statements and other supporting documentation may be found by clicking on the "View Supporting Statement and Other Documents" link. **FOR FURTHER INFORMATION CONTACT:** For specific questions related to collection activities, please contact Don Crews, 202-453-7920.

SUPPLEMENTARY INFORMATION: The Department, in accordance with the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3506(c)(2)(A)), provides the general public and Federal agencies with an opportunity to comment on proposed, revised, and continuing collections of information. This helps the Department assess the impact of its information collection requirements and minimize the public's reporting burden. It also helps the public understand the Department's information collection requirements and provide the requested data in the desired format. ED is soliciting comments on the proposed ICR that is described below. The Department is especially interested in public comments addressing the following issues: (1) is this collection necessary to the proper functions of the Department; (2) will this information be processed and used in a timely manner; (3) is the estimate of burden accurate; (4) how might the Department enhance the quality, utility, and clarity of the information to be collected; and (5) how might the Department minimize the burden of this collection on the respondents, including through the use of information technology. Please note that written comments received in response to this notice will be considered public record.

Title of Collection: Application for grants under the Native American-Serving Nontribal Institutions Program ALN# 84.031X (1894-0001).

OMB Control Number: 1840-0816.

Type of Review: An extension without change of a currently approved ICR.

Respondents/Affected Public: Private Sector.

Total Estimated Number of Annual Responses: 50.

Total Estimated Number of Annual Burden Hours: 2,000.

Abstract: The Title III, Part A Native American-Serving Nontribal Institutions (NASNTI) Program provides grants and related assistance to NASNTI to enable such institutions to plan, develop, undertake, and carry out activities to improve and expand such institutions' capacity to serve Native American and low-income individuals.

This collection is being submitted under the Streamlined Clearance Process for Discretionary Grant Information Collections (1894-0001). Therefore, the 30-day public comment period notice will be the only public comment notice published for this information collection.

Dated: November 17, 2022.

Kun Mullan,

PRA Coordinator, Strategic Collections and Clearance Governance and Strategy Division, Office of Chief Data Officer, Office of Planning, Evaluation and Policy Development.

[FR Doc. 2022-25372 Filed 11-21-22; 8:45 am]

BILLING CODE 4000-01-P

DEPARTMENT OF EDUCATION

[Docket No.: ED-2022-SCC-0113]

Agency Information Collection Activities; Submission to the Office of Management and Budget for Review and Approval; Comment Request; Bipartisan Safer Communities Act (BSA), Stronger Connections Grant (SCG) Program

AGENCY: Office of Elementary and Secondary Education (OESE), Department of Education (ED).

ACTION: Notice.

SUMMARY: In accordance with the Paperwork Reduction Act (PRA) of 1995, the Department is proposing an extension without change of a currently approved information collection request (ICR).

DATES: Interested persons are invited to submit comments on or before December 22, 2022.

ADDRESSES: Written comments and recommendations for proposed information collection requests should be submitted within 30 days of publication of this notice. Click on this link www.reginfo.gov/public/do/PRAMain to access the site. Find this information collection request (ICR) by selecting "Department of Education" under "Currently Under Review," then check the "Only Show ICR for Public Comment" checkbox. *Reginfo.gov* provides two links to view documents related to this information collection request. Information collection forms and instructions may be found by clicking on the "View Information Collection (IC) List" link. Supporting statements and other supporting documentation may be found by clicking on the "View Supporting Statement and Other Documents" link.

FOR FURTHER INFORMATION CONTACT: For specific questions related to collection activities, please contact Bryan Williams, 202-453-6715.

SUPPLEMENTARY INFORMATION: The Department is especially interested in public comment addressing the following issues: (1) is this collection necessary to the proper functions of the Department; (2) will this information be processed and used in a timely manner; (3) is the estimate of burden accurate; (4) how might the Department enhance the quality, utility, and clarity of the information to be collected; and (5) how might the Department minimize the burden of this collection on the respondents, including through the use of information technology. Please note that written comments received in response to this notice will be considered public records.

Title of Collection: Bipartisan Safer Communities Act (BSCA), Stronger Connections Grant (SCG) Program.

OMB Control Number: 1810-0770.

Type of Review: An extension without change of a currently approved ICR.

Respondents/Affected Public: State, local, and Tribal Governments.

Total Estimated Number of Annual Responses: 56.

Total Estimated Number of Annual Burden Hours: 3,360.

Abstract: The Department of Education (the Department) requests an

extension of the information collection under the School Improvement Programs section of the Bipartisan Safer Communities Act (BSCA), and the Stronger Connections Grant (SCG), OMB number 1810-0770. Under this program, the Department awards grants to State educational agencies (SEAs) for the purpose of providing competitive grants to high-need local educational agencies (LEAs) for activities under section 4108 of the Elementary and Secondary Education Act of 1965 (ESEA).

Eligible applicants for the SCG funds include those in any of the 50 States, the District of Columbia, the Commonwealth of Puerto Rico, the Bureau of Indian Education, and the Outlying Areas. Each SEA will award no less than 95 percent of its SCG allocation on a competitive basis to high-need LEAs as determined by the State. The SEA will reserve no more than 1% of its SCG allocation for administration and will use any remaining funds not awarded to LEAs for State-level activities to support section 4108 of the Elementary and Secondary Education Act of 1965 (ESEA).

This information collection will support the Department in providing effective technical assistance, monitoring and oversight to ensure that these funds are awarded and used as required by the BSCA—i.e., that the funds are awarded to high-need LEAs on a competitive basis for activities allowable under section 4108 of the ESEA. Department staff will review the information submitted by SEAs (1) for monitoring purposes, to verify that SEAs are implementing the BSCA requirements for SEA award of the SCG funds; and (2) to understand the manner in which SEAs are implementing these requirements. This information will enable the Department to provide effective technical assistance and support to States. If this information is not collected, the Department will be unable to fully and adequately meet monitoring and technical assistance responsibilities as States implement this program.

Dated: November 17, 2022.

Kun Mullan,

PRA Coordinator, Strategic Collections and Clearance, Governance and Strategy Division, Office of Chief Data Officer, Office of Planning, Evaluation and Policy Development.

[FR Doc. 2022-25441 Filed 11-21-22; 8:45 am]

BILLING CODE 4000-01-P

DEPARTMENT OF EDUCATION

[Docket No.: ED-2022-SCC-0136]

Agency Information Collection Activities; Comment Request; Evaluating the Impact of the Professional Learning Community: Evaluating the Impact of the Professional Learning Community: Emergent Literacy (PLC-EL)

AGENCY: Institute of Education Sciences (IES), Department of Education (ED).

ACTION: Notice.

SUMMARY: In accordance with the Paperwork Reduction Act (PRA) of 1995, the Department is proposing a new information collection request (ICR).

DATES: Interested persons are invited to submit comments on or before January 23, 2023.

ADDRESSES: To access and review all the documents related to the information collection listed in this notice, please use <http://www.regulations.gov> by searching the Docket ID number ED-2022-SCC-0136. Comments submitted in response to this notice should be submitted electronically through the Federal eRulemaking Portal at <http://www.regulations.gov> by selecting the Docket ID number or via postal mail, commercial delivery, or hand delivery. If the *regulations.gov* site is not available to the public for any reason, the Department will temporarily accept comments at ICDocketMgr@ed.gov. Please include the docket ID number and the title of the information collection request when requesting documents or submitting comments. Please note that comments submitted after the comment period will not be accepted. Written requests for information or comments submitted by postal mail or delivery should be addressed to the Manager of the Strategic Collections and Clearance Governance and Strategy Division, U.S. Department of Education, 400 Maryland Ave. SW, LBJ, Room 6W203, Washington, DC 20202-8240.

FOR FURTHER INFORMATION CONTACT: For specific questions related to collection activities, please contact Janelle Sands, 202-245-6786.

SUPPLEMENTARY INFORMATION: The Department, in accordance with the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3506(c)(2)(A)), provides the general public and Federal agencies with an opportunity to comment on proposed, revised, and continuing collections of information. This helps the Department assess the impact of its information collection requirements and

minimize the public's reporting burden. It also helps the public understand the Department's information collection requirements and provide the requested data in the desired format. The Department is soliciting comments on the proposed information collection request (ICR) that is described below. The Department is especially interested in public comment addressing the following issues: (1) is this collection necessary to the proper functions of the Department; (2) will this information be processed and used in a timely manner; (3) is the estimate of burden accurate; (4) how might the Department enhance the quality, utility, and clarity of the information to be collected; and (5) how might the Department minimize the burden of this collection on the respondents, including through the use of information technology. Please note that written comments received in response to this notice will be considered public records.

Title of Collection: Evaluating the Impact of the Professional Learning Community: Emergent Literacy (PLC-EL).

OMB Control Number: 1850-NEW.

Type of Review: A new ICR.

Respondents/Affected Public: Individuals and Households.

Total Estimated Number of Annual Responses: 1,726.

Total Estimated Number of Annual Burden Hours: 3,156.

Abstract: The current authorization for the Regional Educational Laboratories (REL) program is under the Education Sciences Reform Act of 2002, Part D, Section 174, (20 U.S.C. 9564), administered by the Department of Education, Institute of Education Sciences (IES), National Center for Education Evaluation and Regional Assistance (NCEE). The goal of the REL program is to partner with educators and policymakers to conduct work that is change-oriented and supports meaningful local, regional, or state decisions about education policies, programs, and practices to improve outcomes for students.

School readiness, particularly language and literacy readiness, in South Carolina (SC) remains a high-leverage need. This need is reflected in the state's Kindergarten Readiness Assessment (KRA). The KRA measures four domains of learning and development, including language and literacy. Demonstrating readiness occurs when students show the foundational skills and behaviors that prepare them for instruction based on kindergarten standards. In 2020/21 Modified KRA scores in SC revealed that only 27 percent of incoming kindergartners

demonstrated readiness (South Carolina Education Oversight Committee, 2021). Achievement gaps were also observed, with 17 percent of African American kindergartners and 13 percent of Hispanic kindergartners meeting the demonstrating readiness mark, compared to 35 percent of White students. There is a clear need to improve equity in learning opportunities and in school readiness outcomes among SC children. Members of the SC research partnership have identified teacher professional development (PD) in language and literacy as a critical component to improving the quality of early learning and are specifically interested in understanding the effectiveness of and the facilitators and barriers to implementation of the Professional Learning Community: Emergent Literacy (PLC-EL; Kosanovich et al., 2020).

The purpose of this study is to understand the impact of the PLC-EL program on preschool teachers' knowledge, practice, and student achievement in print knowledge, phonological awareness, oral language, and vocabulary. In addition, this study will identify factors that influence program effectiveness and the facilitators and barriers of effective implementation that inform scale-up initiatives across the state. This study will use a randomized controlled trial design to help ensure that—all else equal—this study will yield the strongest, most reliable evidence possible on which to base policy and practice. The study sample will include approximately 100 preschool centers across SC, 2,940 students, 226 preschool teachers, 25 PLC-EL Facilitators, center leaders, and a subset of district and state education leaders.

The study findings will help the Office of Early Learning & Literacy (OELL) at SCDE meet its goals of improving equitable access to high-quality PD for educators and equitable access to high-quality instruction for students by training facilitators to implement the PLC-EL in a large sample of preschool centers in four separate regions of the state. In addition, the study findings will provide the OELL at SCDE with actionable information about facilitators and barriers to implementation that can be used to inform scale-up initiatives across the state.

Dated: November 17, 2022.

Juliana Pearson,

PRA Coordinator, Strategic Collections and Clearance, Governance and Strategy Division, Office of Chief Data Officer, Office of Planning, Evaluation and Policy Development.

[FR Doc. 2022–25434 Filed 11–21–22; 8:45 am]

BILLING CODE 4000–01–P

ELECTION ASSISTANCE COMMISSION

Sunshine Act Meetings

AGENCY: U.S. Election Assistance Commission

ACTION: Sunshine Act Notice; notice of public meeting agenda.

SUMMARY: Public Meeting: U.S. Election Assistance Commission Local Leadership Council Meeting.

DATES: Wednesday, December 14, 2022, 1:00 p.m.–2:30 p.m. Eastern.

ADDRESSES: Virtual via Zoom.

The meeting is open to the public and will be livestreamed on the U.S. Election Assistance Commission YouTube Channel: <https://www.youtube.com/channel/UCpN6i0g2rlF4ITWhwvBwwZw>.

FOR FURTHER INFORMATION CONTACT:

Kristen Muthig, Telephone: (202) 897–9285, Email: kmuthig@eac.gov.

SUPPLEMENTARY INFORMATION:

Purpose: In accordance with the Government in the Sunshine Act (Sunshine Act), Public Law 94–409, as amended (5 U.S.C. 552b), the U.S. Election Assistance Commission (EAC) will conduct a virtual meeting of the EAC Local Leadership Council.

Agenda: The U.S. Election Assistance Commission (EAC) Local Leadership Council will discuss the organizational structure and consider the adoption of the initial committee Bylaws. The Bylaws serve to establish the guidelines for the conduct of the Local Leadership Council members, meetings, and subcommittees. The Bylaws cover several topics including the process for calling and conducting meetings, establishment of committees, the structure of the Executive Committee, the makeup of Regional Committees, and the process of holding elections.

Background: The Local Leadership Council was established in June 2021 under agency authority pursuant to and in accordance with the provisions of the Federal Advisory Committee Act, as amended (5 U.S.C. App. 2). The Advisory Committee is governed by the Federal Advisory Committee Act, which sets forth standards for the formation and use of advisory committees. The

Advisory Committee advises the EAC on how best to fulfill the EAC's statutory duties set forth in 52 U.S.C. 20922 as well as such other matters as the EAC determines. It shall provide a relevant and comprehensive source of expert, unbiased analysis and recommendations to the EAC on local election administration topics.

The Local Leadership Council consists of 100 members. The Election Assistance Commission appoints two members from each state after soliciting nominations from each state's election official professional association. At the time of submission, the Local Leadership Council has 85 appointed members. Upon appointment, Advisory Committee members must be serving or have previously served in a leadership role in a state election official professional association. The full agenda will be posted in advance on the EAC website: <https://www.eac.gov>.

Status: This meeting will be open to the public.

Camden Kelliher,

Associate Counsel, U.S. Election Assistance Commission.

[FR Doc. 2022-25542 Filed 11-18-22; 4:15 pm]

BILLING CODE 6820-KF-P

DEPARTMENT OF ENERGY

Bonneville Power Administration

[BPA File No.: TC-24]

Proposed Modifications To Open Access Transmission Tariff; Public Hearing and Opportunities for Public Review and Comment

AGENCY: Bonneville Power Administration (Bonneville), Department of Energy (DOE).

ACTION: Notice of public hearing and opportunity to review and comment.

SUMMARY: Bonneville is initiating a proceeding pursuant to Bonneville's open access transmission tariff (Tariff) and the Federal Power Act to modify the non-rate terms and conditions for transmission, ancillary, and generator interconnection services in Bonneville's Tariff, to be effective on October 1, 2023. Bonneville has designated this proceeding Docket No. TC-24.

DATES:

Prehearing Conference: The TC-24 tariff proceeding will begin with a prehearing conference, which will be held via telephone on Friday, December 2, 2022.

Intervention: Anyone intending to become a party to the TC-24 tariff proceeding must file a petition to

intervene on Bonneville's secure website. Petitions to intervene may be filed beginning on the date of publication of this Notice and are due no later than 4:30 p.m. on Monday, December 5, 2022.

ADDRESSES: Interested parties may obtain call-in information by accessing Bonneville's TC-24 tariff proceeding web page at <https://www.bpa.gov/goto/tc24> or by contacting the Hearing Clerk at TC24clerk@gmail.com. The TC-24 prehearing conference will begin immediately following the conclusion of the prehearing conference for Bonneville's BP-24 Power and Transmission Rate Proceeding, which begins at 10:00 a.m.

Participant Comments: Written comments by non-party participants must be received by Friday, December 9, 2022 to be considered in the Hearing Officer's recommended decision and the Administrator's Record of Decision (ROD).

Part III of this notice, "Public Participation in TC-24," provides details on requesting access to the secure website, filing a petition to intervene, and submitting participant comments.

FOR FURTHER INFORMATION CONTACT: Ms. Elissa Haley, DKS-7, BPA Communications, Bonneville Power Administration, P.O. Box 3621, Portland, Oregon 97208; by phone toll-free at 1-800-622-4519; or by email to enhaley@bpa.gov.

The Hearing Clerk for this proceeding can be reached via email at TC24clerk@gmail.com or via telephone at (503) 479-8506.

Please direct questions regarding Bonneville's secure website to the Rate Hearing Coordinator via email at cwgriffen@bpa.gov or, if the question is time-sensitive, via telephone at (503) 230-5107.

Responsible Official: Rebecca Fredrickson, Manager of Transmission Rates, Tariff, Regulatory and Compliance, is the official responsible for the development of Bonneville's open access transmission tariff.

SUPPLEMENTARY INFORMATION:

Table of Contents

Part I. Introduction and Procedural Matters
Part II. Scope of TC-24 Terms and Conditions Proceeding
Part III. Public Participation in TC-24
Part IV. Summary of Proposed Modifications to Bonneville's Tariff
Part V. Proposed Tariff

Part I—Introduction and Procedural Matters

A. Introduction

The Bonneville Project Act of 1937, as reaffirmed in the Pacific Northwest Electric Power Planning and Conservation Act, grants the Bonneville Administrator broad authority to enter into contracts upon such terms and conditions and in such manner as the Administrator may deem necessary. Bonneville's Tariff provides the generally applicable terms and conditions for transmission service across the Federal Columbia River Transmission System (FCRTS). Section 9 of the Tariff provides that the Bonneville Administrator may use the procedures set forth in section 212(i)(2)(A) of the Federal Power Act to establish and modify non-rate terms and conditions of the Tariff. Section 212(i)(2)(A) of the Federal Power Act provide procedures the Administrator may use to establish and modify terms and conditions of general applicability for transmission service across the FCRTS. The section 212(i)(2)(A) procedures include giving notice in the **Federal Register** and conducting a hearing that adheres to the procedural requirements of paragraphs (1) through (3) of Section 7(i) of the Northwest Power Act, 16 U.S.C. 839e(i) (the same procedures Bonneville uses to set rates). In accordance with these procedures, the Hearing Officer conducts one or more hearings as expeditiously as practicable to develop a full and complete record. Unless the Hearing Officer becomes unavailable to Bonneville, upon conclusion of the hearing, the Hearing Officer shall make a recommended decision to the Administrator, and the Administrator then makes a separate and final determination to establish or modify the Tariff terms and conditions (discussed further in Part III, Section C of this notice).

Bonneville's Rules of Procedure govern the TC-24 tariff proceedings. The rules are posted on Bonneville's website at <https://www.bpa.gov/energy-and-services/rate-and-tariff-proceedings/rules-of-procedure-revision-process>.

B. Proposed Settlement for Modifications to the Tariff

Since early August, Bonneville engaged its transmission and interconnection customers in an attempt to reach settlement of the modifications to the Tariff for the TC-24 proceeding. These discussions have resulted in the TC-24 Settlement Agreement. Bonneville is proposing to adopt the

TC–24 Settlement Agreement in the TC–24 proceeding. A summary of Bonneville’s proposed Tariff modifications is provided in Part IV of this notice. A link to the full settlement is provided in Part V.

The TC–24 Settlement Agreement calls for Bonneville to file a motion with the Hearing Officer to establish a deadline for parties to either object to the proposed settlement or waive the right to contest the settlement. If no parties object to the settlement by the deadline set by the Hearing Officer, Bonneville’s motion would request the Hearing Officer to issue a decision recommending the Administrator adopt the TC–24 Settlement Agreement. Bonneville intends to file its motion soon after the TC–24 prehearing conference.

If a party objects to the TC–24 Settlement Agreement, Bonneville will notify all parties and decide how to proceed with respect to the Tariff modifications in the initial proposal.

C. Proposed Procedural Schedule

A proposed schedule for the proceeding is provided below and is based on an outcome in which Bonneville’s proposed Tariff is settled. The official schedule will be established by the Hearing Officer and may be amended by the Hearing Officer as needed during the proceeding.

Prehearing Conference—December 2,

2022

BPA Files Initial Proposal—December 2, 2022

Deadline for Petitions to Intervene—December 5, 2022

Deadline for Objections to Settlement Agreement—December 9, 2022

Close of Participant Comments—December 9, 2022

Hearing Officer’s Recommended

Decision Issued—January 13, 2023

Final ROD—February 9, 2023

D. Ex Parte Communications

Section 1010.5 of the Rules of Procedure prohibits *ex parte* communications. *Ex parte* communications include any oral or written communication (1) relevant to the merits of any issue in the proceeding; (2) that is not on the record; and (3) with respect to which reasonable prior notice has not been given. The *ex parte* rule applies to communications with all Bonneville and DOE employees and contractors, the Hearing Officer, and the Hearing Clerk during the proceeding. Except as provided, any communications with persons covered by the rule regarding the merits of any issue in the proceeding by other Executive Branch agencies, Congress,

existing or potential Bonneville customers, nonprofit or public interest groups, or any other non-DOE parties are prohibited. The rule explicitly excludes and does not prohibit communications (1) relating to matters of procedure; (2) otherwise authorized by law or the Rules of Procedure; (3) from or to the Federal Energy Regulatory Commission (Commission); (4) which all litigants agree may be made on an *ex parte* basis; (5) in the ordinary course of business, about information required to be exchanged under contracts, or in information responding to a Freedom of Information Act request; (6) between the Hearing Officer and Hearing Clerk; (7) in meetings for which prior notice has been given; or (8) otherwise specified in Section 1010.5(b) of the Rules of Procedure. The *ex parte* rule remains in effect until the Administrator’s Final ROD is issued.

Part II—Scope of the TC–24 Tariff Proceeding

The TC–24 tariff proceeding is a proceeding for the adoption of modifications to the non-rate terms and conditions in Bonneville’s Tariff. This section provides guidance to the Hearing Officer regarding the specific issues that are outside the scope of the TC–24 tariff proceeding. In addition to the issues specifically listed below, any other issue that is not a Tariff term or condition issue is outside the scope of this proceeding.

Bonneville may revise the scope of the proceeding to include new issues that arise as a result of circumstances or events occurring outside the proceeding that are substantially related to the Tariff terms and conditions under consideration in the proceeding. See Rules of Procedure section 1010.4(b)(8)(iii), (iv). If Bonneville revises the scope of the proceeding to include new issues, Bonneville will provide public notice on its website, present testimony or other information regarding such issues, and provide a reasonable opportunity to intervene and respond to Bonneville’s testimony or other information. *Id.*

A. Business Practices

Bonneville’s business practices provide implementation details for the Tariff and are outside the scope of the TC–24 tariff proceeding. Bonneville’s decisions regarding the business practices are determined in other forums and follow the procedures in Bonneville’s Business Practice Process. If business practices are developed for the proposed terms and conditions in this proceeding, such development will occur outside the terms and conditions

proceeding. Pursuant to section 1010.4(b)(8) of the Rules of Procedure, the Administrator directs the Hearing Officer to exclude from the record all argument, testimony, or other evidence that proposes or challenges Bonneville’s current and future business practices.

B. Customer-Specific Contracts and Disputes

Contracts and contract disputes between Bonneville and its customers are outside the scope of the TC–24 tariff proceeding. Pursuant to section 1010.4(b)(8) of the Rules of Procedure, the Administrator directs the Hearing Officer to exclude from the record all argument, testimony, or other evidence related to contracts and contract disputes of Bonneville customers.

C. Oversupply Management Protocol

The Oversupply Management Protocol (Tariff Attachment P) includes the Tariff requirements and procedures used to moderate total dissolved gas levels in the Columbia River to protect endangered fish and other aquatic species. Bonneville does not propose to modify the terms of the Oversupply Management Protocol in the TC–24 tariff proceeding. Pursuant to section 1010.4(b)(8) of the Rules of Procedure, the Administrator directs the Hearing Officer to exclude from the record all argument, testimony, or other evidence related to the terms of the Oversupply Management Protocol (Tariff Attachment P), including whether the Oversupply Management Protocol complies with orders of the Commission; whether Bonneville took all actions to avoid using the Oversupply Management Protocol, including the payment of negative prices to generators outside of Bonneville’s balancing authority area; and issues concerning the rates for recovering the costs of the Oversupply Management Protocol.

D. Program Cost Estimates

Bonneville’s projections of its program costs and spending levels are not determined in terms and conditions proceedings and are outside the scope of the TC–24 tariff proceeding. These projections are determined by Bonneville in other forums, such as the Integrated Program Review public process, with input from stakeholders. Pursuant to section 1010.4(b)(8) of the Rules of Procedure, the Administrator directs the Hearing Officer to exclude from the record all argument, testimony, or other evidence that challenges the appropriateness or reasonableness of the Administrator’s decisions on costs and spending levels.

E. Rates

Pursuant to Bonneville's statutes, it must set rates to recover costs associated with providing power and transmission services. In addition to and concurrent with this proceeding, Bonneville is holding a separate Power and Transmission Rate Adjustment hearing (the BP-24 proceeding) regarding the proposed fiscal year 2024–2025 power and transmission, ancillary, and control area services rates, including the proposed BP-24 rates settlement agreement. Bonneville's decisions regarding rates are outside the scope of the TC-24 tariff proceeding. Bonneville is publishing a separate notice in the **Federal Register** regarding the BP-24 proceeding. Pursuant to section 1010.4(b)(8) of the Rules of Procedure, the Administrator directs the Hearing Officer to exclude from the record all argument, testimony, or other evidence related to rates, or that challenges the appropriateness or reasonableness of the Administrator's decisions on rates or seeks in any way to propose revisions to the rates, including rate schedules, rate schedule provisions, rate designs, rate methodologies, rate forecasts, interest expense and credit, Treasury repayment schedules, non-Federal debt repayment schedules, revenue financing, calculation of depreciation and amortization expense, forecasts of system replacements used in repayment studies, transmission acquisition expenses incurred by Power Services, generation acquisition expenses, minimum required net revenue, increase in, or the use of, financial reserves, and the costs of risk mitigation actions resulting from the expense and revenue uncertainties included in the risk analysis.

F. Proposed Settlement of the BP-24 Rate Proceeding, FY 2024–2025 Average System Cost Process, and the FY 2022 Power Reserves Distribution Clause Process

The proposed settlement of the BP-24 rate proceeding, FY 2024–2025 Average System Cost Process, and the FY 2022 Power Reserves Distribution Clause Process is outside the scope of the TC-24 tariff proceeding. Pursuant to section 1010.4(b)(8) of the Rules of Procedure, the Administrator directs the Hearing Officer to exclude from the record all argument, testimony, or other evidence related to this proposed settlement.

Part III—Public Participation in TC-24

A. Distinguishing Between “Participants” and “Parties”

Bonneville distinguishes between “participants in” and “parties to” the

TC-24 proceeding. Separate from the formal hearing process, Bonneville will receive written comments, views, opinions, and information from participants, who may submit comments without being subject to the duties of, or having the privileges of, parties. Participants are not entitled to participate in the prehearing conference; may not cross-examine parties' witnesses, seek discovery, or serve or be served with documents; and are not subject to the same procedural requirements as parties. Bonneville customers that will receive transmission or interconnection service under the terms and conditions subject to this proceeding, or their affiliated customer groups, may not submit participant comments. Members or employees of organizations that have intervened in the terms and conditions proceeding may submit participant comments as private individuals (that is, not speaking for their organizations), but may not use the comment procedures to address specific issues raised by their intervener organizations.

Written comments by participants will be included in the record and considered by the Hearing Officer and the Administrator if they are received by Friday, December 9, 2022. The proposed Tariff and attachments are provided in Section V of this notice. Participants should submit comments through Bonneville's website at www.bpa.gov/comment or in hard copy to: BPA Public Involvement, DKS-7, Bonneville Power Administration, P.O. Box 3621, Portland, Oregon 97208. All comments should contain the designation “TC-24” in the subject line.

B. Interventions

Any entity or person intending to become a party in the TC-24 proceeding must file a petition to intervene through Bonneville's secure website (<https://ratecase.bpa.gov/>). A first-time user of Bonneville's secure website must create a user account to submit an intervention. Returning users may request access to the TC-24 proceeding through their existing accounts, and may submit interventions once their permissions have been updated. The secure website contains a link to the user guide, which provides step-by-step instructions for creating user accounts, generating filing numbers, submitting filings, and uploading interventions. Please contact the Hearing Coordinator via email at cwgriffen@bpa.gov or, if the question is time-sensitive, via telephone at (503) 230-5107 with any questions regarding the submission process. A petition to intervene must conform to the format and content requirements set

forth in Bonneville's Rules of Procedure sections 1010.6 and 1010.11 and must be uploaded to the TC-24 proceeding secure website by the deadline established in the procedural schedule.

A petition to intervene must state the name and address of the entity or person requesting party status and the entity or person's interest in the hearing. Bonneville customers and affiliated customer groups will be granted intervention based on petitions filed in conformance with Rules of Procedure. Other petitioners must explain their interests in sufficient detail to permit the Hearing Officer to determine whether the petitioners have a relevant interest in the hearing. The deadline for opposing a timely intervention is two business days after the deadline for filing petitions to intervene. Bonneville or any party may oppose a petition for intervention. All petitions will be ruled on by the Hearing Officer. Late interventions are strongly disfavored. Opposition to an untimely petition to intervene must be filed within two business days after service of the petition.

C. Developing the Record

The hearing record will include, among other things, the transcripts of the hearing, written evidence and arguments entered into the record by Bonneville and the parties, written comments from participants, and other material accepted into the record by the Hearing Officer. Upon conclusion of the hearing, the Hearing Officer will develop a recommended decision for the Administrator. The Hearing Officer's recommended decision must be based on the record and include the Hearing Officer's findings and conclusions, including the reasons or bases thereof, on all material issues of fact, law, or discretion raised by the parties in their initial briefs. The Hearing Officer will review and certify the record to the Administrator for final decision.

The Administrator will make a final determination establishing or modifying Tariff terms and conditions based on the record, the Hearing Officer's recommended decision, and such other materials and information as may have been submitted to or developed by the Administrator. The Final ROD will be made available to all parties.

Part IV—Summary of Proposed Modifications to Bonneville's Tariff

In this proceeding, Bonneville proposes to modify the non-rate Tariff terms and conditions consistent with the Tariff attached to the TC-24 Settlement Agreement, to be effective on October 1, 2023. The TC-24 Settlement

Agreement includes (1) changes to the conditional reservation deadlines for hourly firm and daily firm point-to-point services; (2) maintaining the use of two season loss factors for the Network segment, updating the two season loss factors percentages, and removing the Utility Delivery and DSI loss factors from Schedule 11; (3) updating the description of BPA's ATC methodologies in Attachment C and specifying that BPA will stop maintaining a long-term ATC methodology for the long-term planning horizon on the flow-based paths and instead use commercial power flow studies to evaluate new transmission service requests; (4) modifying the large generator interconnection request template in Appendix 1 to Attachment L, Large Generator Interconnection Procedures, (5) clarifications to Attachment Q, Energy Imbalance Market, including adding a reference to the rate schedules that would be used under certain EIM contingencies, clarifying forecast data requirements, and updating the location of BPA outage requirements; (6) ministerial edits; and (7) other process-related commitments. The proposed Tariff assumes the TC-24 settlement is successful. In the event the TC-24 settlement is unsuccessful, Bonneville will publish a revised Tariff proposal consistent with the procedural schedule established and amended by the Hearing Officer.

Part V—Proposed Tariff

Bonneville's proposed Tariff and the TC-24 Settlement Agreement is part of this notice and is available to view and download on Bonneville's website at <https://www.bpa.gov/goto/TC24>.

Signing Authority

This document of the Department of Energy was signed on November 8, 2022, by John L. Hairston, Administrator and Chief Executive Officer of the Bonneville Power Administration, pursuant to delegated authority from the Secretary of Energy. This document with the original signature and date is maintained by DOE. For administrative purposes only, and in compliance with requirements of the Office of the Federal Register, the undersigned DOE Federal Register Liaison Officer has been authorized to sign and submit the document in electronic format for publication, as an official document of the Department of Energy. This administrative process in no way alters the legal effect of this document upon publication in the **Federal Register**.

Signed in Washington, DC, on November 17, 2022.

Treena V. Garrett,

Federal Register Liaison Officer, U.S. Department of Energy.

[FR Doc. 2022-25374 Filed 11-21-22; 8:45 am]

BILLING CODE 6450-01-P

DEPARTMENT OF ENERGY

DOE/NSF High Energy Physics Advisory Panel

AGENCY: Department of Energy, Office of Science.

ACTION: Notice of open meeting.

SUMMARY: This notice announces a hybrid meeting of the DOE/NSF High Energy Physics Advisory Panel (HEPAP). The Federal Advisory Committee Act requires that public notice of these meetings be announced in the **Federal Register**.

DATES:

Thursday, December 8, 2022; 8:00 a.m. to 5:00 p.m.

Friday, December 9, 2022; 8:00 a.m. to 2:00 p.m.

ADDRESSES: This meeting is open to the public. This meeting will be held at the Doubletree by Hilton at 620 Perry Parkway, Gaithersburg, MD 20877. Participation through ZOOM will also be available. Information to participate can be found on the website closer to the meeting date at <https://science.osti.gov/hep/hepap/meetings/>.

FOR FURTHER INFORMATION CONTACT: John Kogut, Executive Secretary; High Energy Physics Advisory Panel (HEPAP); U.S. Department of Energy; Office of Science; SC-35/Germantown Building, 1000 Independence Avenue SW, Washington, DC 20585; Telephone: (301) 903-1298; Email: John.Kogut@science.doe.gov.

SUPPLEMENTARY INFORMATION:

Purpose of Meeting: To introduce the new Associate Director of the Office of High Energy Physics, Dr. Regina Rameika, and to charge HEPAP to constitute a new Particle Physics Project Prioritization Panel (P5) panel to develop an updated strategic plan for U.S. high-energy physics.

Tentative Agenda

- Update from DOE—Regina Rameika
- Update from NSF—Denise Caldwell
- Presentation of P5 Charge—Glen Crawford/Regina Rameika
- Discussion

Public Participation: The meeting is open to the public. A webcast of this meeting will be available. Please check the website below for updates and information on how to view the meeting. If you would like to file a

written statement with the Committee, you may do so either before or after the meeting. If you would like to make oral statements regarding any of these items on the agenda, you should contact John Kogut, (301) 903-1298 or by email at John.Kogut@science.doe.gov. You must make your request for an oral statement at least five business days before the meeting. Reasonable provisions will be made to include the scheduled oral statements on the agenda. The Chairperson of the Panel will conduct the meeting to facilitate the orderly conduct of business. Public comment will follow the 10-minute rule.

Minutes: The minutes of the meeting will be available on the High Energy Physics Advisory Panel website at <https://science.osti.gov/hep/hepap/meetings/>.

Signed in Washington, DC, on November 16, 2022.

LaTanya Butler,

Deputy Committee Management Officer.

[FR Doc. 2022-25338 Filed 11-21-22; 8:45 am]

BILLING CODE 6450-01-P

DEPARTMENT OF ENERGY

National Petroleum Council; Meeting

AGENCY: Office of Fossil Energy and Carbon Management, Department of Energy.

ACTION: Notice of open meeting.

SUMMARY: This notice announces a meeting of the National Petroleum Council. The Federal Advisory Committee Act requires that public notice of this meeting be announced in the **Federal Register**.

DATES: Wednesday, December 14, 2022, 9 a.m. to no later than 11:30 a.m. (EST).

ADDRESSES: Willard InterContinental Hotel, 1401 Pennsylvania Avenue NW, Washington, DC 20004. In-person meeting. Information to access a live stream of the meeting proceedings will be available at: www.energy.gov/fecm/national-petroleum-council-npc.

FOR FURTHER INFORMATION CONTACT:

Nancy Johnson, U.S. Department of Energy, Office of Resource Sustainability (FECM-30), 1000 Independence Avenue SW, Washington, DC 20585; telephone: (202) 586-6458 or email: nancy.johnson@hq.doe.gov.

SUPPLEMENTARY INFORMATION:

Purpose of the Committee: To provide advice, information, and recommendations to the Secretary of Energy on matters relating to oil and natural gas, and the oil and natural gas industries.

Tentative Agenda

- Call to Order and Introductory Remarks
- Department of Energy Remarks
- Consideration of the Proposed Final Report of the NPC Committee on Short-Term Actions and Transition Strategies
- Progress Reports from the NPC Hydrogen Energy and GHG Emissions Committees
- Administrative Matters
- Discussion of Any Other Business Properly Brought Before the National Petroleum Council
- Adjournment

Public Participation: The meeting is open to the public. The Chair of the Council will conduct the meeting to facilitate the orderly conduct of business. Members of the public who wish to make oral statements pertaining to agenda items should contact Ms. Nancy Johnson at the address or telephone number listed above. Approximately 15 minutes will be reserved for public comments. The time allocated per speaker will depend on the number of requests received, but will not exceed five minutes. Requests for oral statements must be received at least seven days prior to the meeting. Those not able to attend the meeting or having insufficient time to address the Council are invited to send a written statement to nancy.johnson@hq.doe.gov. Any member of the public who wishes to file a written statement to the Council will be permitted to do so, either before or after the meeting.

Minutes: The minutes of the meeting will be available at <https://www.energy.gov/fecm/national-petroleum-council-npc> or by contacting Ms. Johnson. She may be reached at the above postal address or email address.

Signed in Washington, DC, on November 16, 2022.

LaTanya Butler,

Deputy Committee Management Officer.

[FR Doc. 2022–25339 Filed 11–21–22; 8:45 am]

BILLING CODE 6450–01–P

DEPARTMENT OF ENERGY**Federal Energy Regulatory Commission****Combined Notice of Filings**

Take notice that the Commission has received the following Natural Gas Pipeline Rate and Refund Report filings:

Filings Instituting Proceedings

Docket Numbers: CP20–70–000; CP20–68–000.

Applicants: Enable Gas Transmission, LLC.

Description: Enable Gas Transmission, LLC and Enable Gulf Run Transmission, LLC submits Amended and Restated Capacity Lease Agreement under CP20–68, et. al.

Filed Date: 09/28/2022.

Accession Number: 20220928–5148.

Comment Date: 5 p.m. ET 11/22/22.

Docket Numbers: RP23–191–000.

Applicants: Enable Gas Transmission, LLC.

Description: § 4(d) Rate Filing: Tariff Revisions to be effective 12/15/2022.

Filed Date: 11/15/22.

Accession Number: 20221115–5136.

Comment Date: 5 p.m. ET 11/28/22.

Docket Numbers: RP23–192–000.

Applicants: El Paso Natural Gas Company, L.L.C.

Description: § 4(d) Rate Filing: Article 11.2(a) Inflation Adjustment Filing 2023 to be effective 1/1/2023.

Filed Date: 11/15/22.

Accession Number: 20221115–5169.

Comment Date: 5 p.m. ET 11/28/22.

Docket Numbers: RP23–193–000.

Applicants: Mojave Pipeline Company, L.L.C.

Description: § 4(d) Rate Filing: Annual Fuel and L&U Filing 2023 to be effective 1/1/2023.

Filed Date: 11/16/22.

Accession Number: 20221116–5057.

Comment Date: 5 p.m. ET 11/28/22.

Any person desiring to intervene or protest in any of the above proceedings must file in accordance with Rules 211 and 214 of the Commission's Regulations (18 CFR 385.211 and 385.214) on or before 5:00 p.m. Eastern time on the specified comment date. Protests may be considered, but intervention is necessary to become a party to the proceeding.

The filings are accessible in the Commission's eLibrary system (<https://elibrary.ferc.gov/idmws/search/fercensearch.asp>) by querying the docket number.

eFiling is encouraged. More detailed information relating to filing requirements, interventions, protests, service, and qualifying facilities filings can be found at: <http://www.ferc.gov/docs-filing/efiling/filing-req.pdf>. For other information, call (866) 208–3676 (toll free). For TTY, call (202) 502–8659.

Dated: November 16, 2022.

Debbie-Anne A. Reese,

Deputy Secretary.

[FR Doc. 2022–25399 Filed 11–21–22; 8:45 am]

BILLING CODE 6717–01–P

ENVIRONMENTAL PROTECTION AGENCY

[EPA–HQ–OPP–2022–0222; FRL–10372–01–OCSPP]

Notice of Receipt of Requests To Voluntarily Cancel Certain Pesticide Registrations and Amend Registrations To Terminate Certain Uses

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: In accordance with the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), EPA is issuing a notice of receipt of requests by the registrants to voluntarily cancel certain product registrations and to amend certain product registrations to terminate one or more uses. EPA intends to grant these requests at the close of the comment period for this announcement unless the Agency receives substantive comments within the comment period that would merit its further review of the requests, or unless the registrants withdraw its requests. If these requests are granted, any sale, distribution, or use of products listed in this notice will be permitted after the registrations have been cancelled or uses terminated only if such sale, distribution, or use is consistent with the terms as described in the final order.

DATES: Comments must be received on or before December 22, 2022.

ADDRESSES: Submit your comments, identified by docket identification (ID) number EPA–HQ–OPP–2022–0222, through the Federal eRulemaking Portal at <https://www.regulations.gov>. Follow the online instructions for submitting comments. Do not submit electronically any information you consider to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Additional instructions on commenting and visiting the docket, along with more information about dockets generally, is available at <https://www.epa.gov/dockets>.

FOR FURTHER INFORMATION CONTACT:

Christopher Green, Registration Division (7505T), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave. NW, Washington, DC 20460–0001; telephone number: (202) 566–2707; email address: green.christopher@epa.gov.

SUPPLEMENTARY INFORMATION:**I. General Information**

A. Does this action apply to me?

This action is directed to the public in general and may be of interest to a

wide range of stakeholders including environmental, human health, and agricultural advocates; the chemical industry; pesticide users; and members of the public interested in the sale, distribution, or use of pesticides. Since others also may be interested, the Agency has not attempted to describe all the specific entities that may be affected by this action.

B. What should I consider as I prepare my comments for EPA?

1. *Submitting CBI.* Do not submit this information to EPA through [regulations.gov](https://www.epa.gov/regulations.gov) or email. Clearly mark the part or all of the information that you claim to be CBI. For CBI

information in a disk or CD-ROM that you mail to EPA, mark the outside of the disk or CD-ROM as CBI and then identify electronically within the disk or CD-ROM the specific information that is claimed as CBI. In addition to one complete version of the comment that includes information claimed as CBI, a copy of the comment that does not contain the information claimed as CBI must be submitted for inclusion in the public docket. Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR part 2.

2. *Tips for preparing your comments.* When preparing and submitting your comments, see the commenting tips at

<https://www.epa.gov/dockets/commenting-epa-dockets>.

II. What action is the Agency taking?

This notice announces receipt by EPA of requests from registrants to cancel certain pesticide product registrations and terminate certain uses of product registrations. The affected products and the registrants making the requests are identified in Tables 1–3 of this unit.

Unless a request is withdrawn by the registrant or if the Agency determines that there are substantive comments that warrant further review of this request, EPA intends to issue an order canceling and amending the affected registrations.

TABLE 1—PRODUCT REGISTRATIONS WITH PENDING REQUESTS FOR CANCELLATION

Registration No.	Company No.	Product name	Active ingredients
228–713	228	TVC—Consumer Concentrate	Glyphosate-Isopropylammonium (103601/38641–94–0)—(5.03%), Imazapyr, Isopropylamine Salt (128829/81510–83–0)—(.089%).
228–714	228	TVC Consumer RTU	Glyphosate-Isopropylammonium (103601/38641–94–0)—(1.02%), Imazapyr, Isopropylamine Salt (128829/81510–83–0)—(.018%).
264–1156	264	QRD 406	Chenopodium Ambrosioides Var. Ambrosioides (599995/89997–47–7)—(100%).
264–1157	264	QRD 400	Chenopodium Ambrosioides Var. Ambrosioides (599995/89997–47–7)—(25%).
264–1187	264	Oberon Speed	Abamectin (122804/71751–41–2)—(1.08%), Spiromesifen (024875/283594–90–1)—(21.57%).
352–590	352	Dupont Cover Herbicide	Sulfentrazone (129081/122836–35–5)—(75%).
499–488	499	TC 223	Diffubenzuron (108201/35367–38–5)—(.25%).
499–501	499	Prescription Treatment Brand PT 224B	Propoxur (047802/114–26–1)—(1%).
524–543	524	Mon 78481 Herbicide	Carfentrazone-Ethyl (128712/128639–02–1)—(.19%), Glycine, N-(Phosphonomethyl)- Potassium Salt (103613/70901–12–1)—(44.76%).
707–304	707	Rocima 65 Industrial Microbicide	1,3,5-Triazine-2,4-Diamine, N-Cyclopropyl-N'-(1,1-Dimethylethyl)-6-(Methylthio)- (128996/28159–98–0)—(3.5%), 3(2h)-Isothiazolone, 4,5-Dichloro-2-Octyl- (128101/64359–81–5)—(5%), Carbendazim (128872/10605–21–7)—(9%).
1381–198	1381	Execute S–P Insecticide	Pirimiphos-Methyl (108102/29232–93–7)—(57%), Spinosad (110003/131929–60–7)—(22.8%).
1381–221	1381	Imid+Meta+Tebu	Imidacloprid (129099/138261–41–3)—(12.7%), Metalaxyl (113501/57837–19–1)—(.82%), Tebuconazole (128997/107534–96–3)—(.62%).
1381–242	1381	IMT ST	Imidacloprid (129099/138261–41–3)—(11.374%), Metalaxyl (113501/57837–19–1)—(.607%), Tebuconazole (128997/107534–96–3)—(.455%).
8329–72	8329	Mosquito Larvicide GB–1111	Mineral Oil—Includes Paraffin Oil From 063503 (063502/8012–95–1)—(98.7%).
10163–230	10163	Mesuro Technical Insecticide	Methiocarb (100501/2032–65–7)—(98.8%).
10163–231	10163	Mesuro 75–W	Methiocarb (100501/2032–65–7)—(75%).
28293–123	28293	Unicorn Malathion Spray 1	Malathion (No Inert Use) (057701/121–75–5)—(57%).
34704–853	34704	Treflan 4L Herbicide	Trifluralin (036101/1582–09–8)—(43%).
34704–872	34704	Ginmaster Cotton Defoliant	Diuron (035505/330–54–1)—(6%), Thidiazuron (120301/51707–55–2)—(12%).
34704–895	34704	Colt	Clpyralid, Monoethanolamine Salt (117401/57754–85–5)—(11.3%), Fluroxypyr-Meptyl (128968/81406–37–3)—(12.3%).
34704–1004	34704	LPI Chlor-Metsul	Chlorsulfuron (118601/64902–72–3)—(62.5%), Metsulfuron (122010/74223–64–6)—(12.5%).
35935–94	35935	TVC -Super Concentrate	Glyphosate (417300/1071–83–6)—(43.68%), Imazapyr (128821/81334–34–1)—(.78%).
40810–11	40810	Irgarol 1051	1,3,5-Triazine-2,4-Diamine, N-Cyclopropyl-N'-(1,1-Dimethylethyl)-6-(Methylthio)- (128996/28159–98–0)—(98.6%).

TABLE 1—PRODUCT REGISTRATIONS WITH PENDING REQUESTS FOR CANCELLATION—Continued

Registration No.	Company No.	Product name	Active ingredients
40810–15	40810	Irgarol 1071	1,3,5-Triazine-2,4-Diamine, N-Cyclopropyl-N'-(1,1-Dimethylethyl)-6-(Methylthio)- (128996/28159–98–0)—(98.6%).
47000–107	47000	Prozap Malathion 57% Emulsifiable Liquid Insecticide-B.	Malathion (No Inert Use) (057701/121–75–5)—(57%).
66222–240	66222	Mana Diflubenzuron 80WG	Diflubenzuron (108201/35367–38–5)—(80%).
83822–1	83822	Weed2 & Feed Mulch	Dithiopyr (128994/97886–45–8)—(.0002%), Isoxaben (125851/82558–50–7)—(.0005%).
AR–100001	279	Spartan Charge Herbicide	Carfentrazone-ethyl 3.53% Sulfentrazone 31.77%.
CA–170004	62719	Sequoia (Alternate), Closer SC (Active)	Sulfoxaflor 21.8%.
CA–170009	71693	Aspergillus Flavus AF36 Prevail	Aspergillus flavus strain AF36 .0008%.
FL–070003	62719	Cleanwave	Aminopyralid-Tripromine (005209/566191–89–7)—(1.92%), Fluroxypyr-Meptyl (128968/81406–37–3)—(20.22%).
KS–220002	264	USH0720®	Flufenacet (121903/142459–58–3)—(28.5%), Isoxaflutole (123000/141112–29–0)—(5.7%), Thiencarbazone-Methyl (015804/317815–83–1)—(2.28%).
MO–220001	264	USH0720®	Flufenacet (121903/142459–58–3)—(28.5%), Isoxaflutole (123000/141112–29–0)—(5.7%), Thiencarbazone-Methyl (015804/317815–83–1)—(2.28%).
WA–210002	62719	Entrust SC	Spinosad 22.5%.
WI–130002	62719	Starane Ultra Herbicide	Fluroxypyr-meptyl 45.52%.
WI–150002	62719	Starane Ultra Herbicide	Fluroxypyr-meptyl 45.52%.

TABLE 2—PRODUCT REGISTRATIONS WITH PENDING REQUESTS FOR USE TERMINATIONS

Registration No.	Company No.	Product name	Active ingredient	Uses to be terminated
1021–2720	1021	Pramix Technical Insecticide	Permethrin (109701/52645–53–1)—(95%).	Wood Treatment & Protection Uses.
1021–2741	1021	Pramex Tech I	Permethrin (109701/52645–53–1)—(94%).	Wood Treatment & Protection Uses.
1021–2748	1021	Pramex B Technical Insecticide	Permethrin (109701/52645–53–1)—(96.1%).	Wood Treatment & Protection Uses.
1021–2772	1021	Pramex TG	Permethrin (109701/52645–53–1)—(95.5%).	Wood Treatment & Protection Uses.
1021–2775	1021	Pramex 98.5% TG	Permethrin (109701/52645–53–1)—(98.5%).	Wood Treatment & Protection Uses.
5905–595	5905	Ethephon 3#	Citric Acid (I) (821801/77–92–9)—(%), Ethephon (A) (099801/16672–87–0)—(27%), Toluene (See Comments) (I) (880601/108–88–3)—(%), Water (I) (800001/7732–18–5)—(%), Xylene (I) (886802/1330–20–7)—(%).	Uses on residential turf/lawns, institutional turf, parks, recreational fields or sod farms.
5905–615	5905	Omni Brand Ethephon 2 lb	Ethephon (A) (099801/16672–87–0)—(21.7%), Water (I) (800001/7732–18–5)—(70.6%).	Uses on residential turf/lawns, institutional turf, parks, recreational fields or sod farms.
35935–81	35935	NuFarm Ethephon MUP	Ethephon (099801/16672–87–0)—(75%).	Non-Golf Turf Uses.
66222–151	66222	Ethephon 2SL	Ethephon (099801/16672–87–0)—(21.7%).	Turf Uses.
69969–7	69969	AV–5055	Anthraquinone (122701/84–65–1)—(18.6%).	Municipal Sites, Urban Areas, Sports Fields, Park Grounds, Home Lawns & Golf Courses.
69969–8	69969	Anthraquinone Technical	Anthraquinone (122701/84–65–1)—(99.68%).	Municipal Sites, Urban Areas, Sports Fields, Park Grounds, Residential Buildings/Home Lawns & Golf Courses.
70506–459	70506	Ethephon 2#	Ethephon (099801/16672–87–0)—(21.7%).	Use on Institutional Turf.
70506–464	70506	Ethephon 3.9% H&G	Ethephon (099801/16672–87–0)—(3.9%).	Uses on Lawns and Parks.

Table 3 of this unit includes the names and addresses of record for the registrants of the products listed in

Table 1 and Table 2 of this unit, in sequence by EPA company number. This number corresponds to the first

part of the EPA registration numbers of the products listed in Table 1 and Table 2 of this unit.

TABLE 3—REGISTRANTS REQUESTING VOLUNTARY CANCELLATION AND/OR USE TERMINATIONS

EPA company No.	Company name and address
228	NuFarm Americas, Inc. 4020 Aerial Center Pkwy., Ste. 101 Morrisville, NC 27560.
264	Bayer CropScience, LP Agent: Bayer CropScience, LLC 801 Pennsylvania Avenue, Suite 900, Washington, DC 20004.
279	FMC Corporation, 2929 Walnut Street, Philadelphia, PA 19104.
352	Corteva Agriscience, LLC, 9330 Zionsville Road, Indianapolis, IN 46268.
499	BASF Corporation, 26 Davis Drive, Research Triangle Park, NC 27709–3528.
524	Bayer CropScience, LP, 801 Pennsylvania Ave. NW, Suite 900, Washington, DC 20004.
707	Nutrition & Biosciences USA 2, LLC, 1652 Larkin Center Drive, 100 Larkin Center, Midland, MI 48642.
1021	McLaughlin Gormley King Company, D/B/A MGK, 7325 Aspen Lane N, Minneapolis, MN 55428.
1381	Winfield Solutions, LLC, P.O. Box 64589, St. Paul, MN 55164–0589.
5905	Helena Agri-Enterprises, LLC, D/B/A Helena Chemical Comp, 225 Schilling Blvd., Suite 300, Collierville, TN 38017.
8329	Clarke Mosquito Control Products, Inc., 675 Sidwell Court, St. Charles, IL 60174.
10163	Gowan Company, LLC, 370 S. Main St., Yuma, AZ 85366.
28293	Phaeton Corp., D/B/A Unicorn Laboratories, 1501 E Woodfield Road, Suite 200W, Schaumburg, IL 60173.
34704	Loveland Products, Inc., Agent: Pyxis Regulatory Consulting, Inc., 4110 136th Street CT NW, Gig Harbor, WA 98332.
35935	NuFarm Limited, Agent: NuFarm Americas, Inc., 4020 Aerial Center Pkwy., Ste. 101, Morrisville, NC 27560.
40810	BASF Corporation, 100 Park Avenue, Florham Park, NJ 07932.
47000	Chem-Tech, Ltd., 620 Leshner Place, Lansing, MI 48912.
62719	Corteva Agriscience, LLC, 9330 Zionsville Road, Indianapolis, IN 46268.
66222	Makhteshim Agan of North America, Inc., D/B/A Adama, 3120 Highwoods Blvd., Suite 100, Raleigh, NC 27604.
69969	Arkion Life Sciences, LLC, Agent Name: Wagner Regulatory Associates, Inc., P.O. Box 640, Hockessin, DE 19707.
70506	UPL NA, Inc., 630 Freedom Business Center, Suite 402, King of Prussia, PA 19406.
71693	Arizona Cotton Research and Protection Council, Agent Name: IR–4 Project, Rutgers University, 500 College Road East, Suite 201W Princeton, NJ 08540.
83822	Mulch Manufacturing, Inc., 6747 Taylor Road SW, Reynoldsburg, OH 43068.
89969	Arkion Life Sciences, LLC, Agent Name: Wagner Regulatory Associates, Inc., P.O. Box 640, Hockessin, DE 19707.

III. What is the Agency's authority for taking this action?

Section 6(f)(1) of FIFRA (7 U.S.C. 136d(f)(1)) provides that a registrant of a pesticide product may at any time request that any of its pesticide registrations be canceled or amended to terminate one or more uses. FIFRA further provides that, before acting on the request, EPA must publish a notice of receipt of any such request in the **Federal Register**.

Section 6(f)(1)(B) of FIFRA (7 U.S.C. 136d(f)(1)(B)) requires that before acting on a request for voluntary cancellation, EPA must provide a 30-day public comment period on the request for voluntary cancellation or use termination. In addition, FIFRA section 6(f)(1)(C) (7 U.S.C. 136d(f)(1)(C)) requires that EPA provide a 180-day comment period on a request for voluntary cancellation or termination of any minor agricultural use before granting the request, unless:

1. The registrants request a waiver of the comment period, or

2. The EPA Administrator determines that continued use of the pesticide would pose an unreasonable adverse effect on the environment.

The registrants have requested that EPA waive the 180-day comment period.

Accordingly, EPA will provide a 30-day comment period on the proposed requests.

IV. Procedures for Withdrawal of Requests

Registrants who choose to withdraw a request for product cancellation or use deletion should submit the withdrawal in writing to the person listed under **FOR FURTHER INFORMATION CONTACT**. If the products have been subject to a previous cancellation action, the effective date of cancellation and all other provisions of any earlier cancellation action are controlling.

V. Provisions for Disposition of Existing Stocks

Existing stocks are those stocks of registered pesticide products that are currently in the United States and that

were packaged, labeled, and released for shipment prior to the effective date of the action. If the requests for voluntary cancellation and amendments to terminate uses are granted, the Agency intends to publish the cancellation order in the **Federal Register**.

In any order issued in response to these requests for cancellation of product registrations and for amendments to terminate uses, EPA proposes to include the following provisions for the treatment of any existing stocks of the products listed in Tables 1 and 2 of Unit II.

For voluntary product cancellations, listed in Table 1 of Unit II, registrants will be permitted to sell and distribute existing stocks of voluntarily canceled products for 1 year after the effective date of the cancellation, which will be the date of publication of the cancellation order in the **Federal Register**. Thereafter, registrants will be prohibited from selling or distributing the products identified in Table 1 of Unit II, except for export consistent with FIFRA section 17 (7 U.S.C. 136o) or for proper disposal.

Once EPA has approved product labels reflecting the requested amendments to terminate uses, registrants will be permitted to sell or distribute products under the previously approved labeling for a period of 18 months after the date of **Federal Register** publication of the cancellation order, unless other restrictions have been imposed. Thereafter, registrants will be prohibited from selling or distributing the products whose labels include the terminated uses identified in Table 2 of Unit II, except for export consistent with FIFRA section 17 or for proper disposal.

Persons other than the registrant may sell, distribute, or use existing stocks of canceled products and products whose labels include the terminated uses until supplies are exhausted, provided that such sale, distribution, or use is consistent with the terms of the previously approved labeling on, or that accompanied, the canceled products and terminated uses.

Authority: 7 U.S.C. 136 *et seq.*

Dated: November 15, 2022.

Daniel Rosenblatt,

Acting Director, Registration Division, Office of Pesticide Programs.

[FR Doc. 2022-25428 Filed 11-21-22; 8:45 am]

BILLING CODE 6560-50-P

ENVIRONMENTAL PROTECTION AGENCY

[EPA-HQ-OPP-2022-0222; FRL-10288-01-OCSPP]

Cancellation Order for Certain Pesticide Registrations and Amendments To Terminate Uses

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: This notice announces EPA's order for the cancellations and amendments to terminate uses, voluntarily requested by the registrants and accepted by the Agency, of certain product registrations, pursuant to the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA). This cancellation order follows an August 29, 2022, **Federal Register** Notice of Receipt of Requests from the registrants listed in Table 3 of Unit II, to voluntarily cancel and amend certain product registrations to terminate uses of these product registrations. In the August 29, 2022, notice, EPA indicated that it would issue an order implementing the cancellations and amendments to terminate uses, unless the Agency received substantive comments within the 30-day comment period that would merit its further review of these requests, or unless the registrants withdrew their requests. The Agency did not receive any comments on the notice. Further, the registrants did not withdraw their requests. Accordingly, EPA hereby issues in this notice a cancellation order granting the requested cancellations and amendments to terminate uses. Any distribution, sale, or use of the products subject to this cancellation order is permitted only in accordance with the terms of this order, including any existing stocks provisions.

DATES: The cancellations and amendments are effective November 22, 2022.

FOR FURTHER INFORMATION CONTACT:

Christopher Green, Registration Division (7505T), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave. NW, Washington, DC 20460-0001; telephone number: (202) 566-2707; email address: green.christopher@epa.gov.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this action apply to me?

This action is directed to the public in general and may be of interest to a wide range of stakeholders including environmental, human health, and agricultural advocates; the chemical industry; pesticide users; and members of the public interested in the sale, distribution, or use of pesticides. Since others also may be interested, the Agency has not attempted to describe all the specific entities that may be affected by this action.

B. How can I get copies of this document and other related information?

The docket for this action, identified by docket identification (ID) number EPA-HQ-OPP-2022-0222, is available at <https://www.regulations.gov> or at the Office of Pesticide Programs Regulatory Public Docket (OPP Docket) in the Environmental Protection Agency Docket Center (EPA/DC), West William Jefferson Clinton Bldg., Rm. 3334, 1301 Constitution Ave. NW, Washington, DC 20460-0001. The Public Reading Room is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Public Reading Room is (202) 566-1744, and the telephone number for the OPP Docket is (202) 566-1744. Please review the visitor instructions and additional information about the docket available at <https://www.epa.gov/dockets>.

II. What action is the Agency taking?

This notice announces the cancellations and amendments to terminate uses, as requested by registrants, of products registered under FIFRA section 3 (7 U.S.C. 136a). These registrations are listed in sequence by registration number in Tables 1 and 2 of this unit.

TABLE 1—PRODUCT CANCELLATIONS

Registration No.	Company No.	Product name	Active ingredients
100-1238	100	Scimitar GR Insecticide	Lambda-Cyhalothrin.
100-1239	100	Lambda-CY 0.045% H&G Granule Insecticide	Lambda-Cyhalothrin.
100-1273	100	A14796 Insecticide	Lambda-Cyhalothrin.
100-1274	100	A14797 Insecticide	Lambda-Cyhalothrin.
100-1304	100	Thiamethoxam 0.20/Lambda-Cyhalothrin 0.04 L&G GR.	Lambda-Cyhalothrin & Thiamethoxam.
100-1334	100	Thiamethoxam 0.40/Lambda-cyhalothrin 0.16 ME Concentrate.	Lambda-Cyhalothrin & Thiamethoxam.
100-1336	100	Thiamethoxam 0.010/Lambda-cyhalothrin 0.004 ME RTU.	Lambda-Cyhalothrin & Thiamethoxam.
228-649	228	NuFarm Two Ox Pro Herbicide	Oxadiazon & Oxyfluorfen.
1381-180	1381	Pro Source #1 Magic Carpet Fertilizer with 0.67% Ronstar.	Oxadiazon.
1381-181	1381	Pro Source Magic Carpet Fertilizer with 1.00% Ronstar.	Oxadiazon.
2693-195	2693	VC17M with Biolux Copper Powder V901	Copper as elemental.

TABLE 1—PRODUCT CANCELLATIONS—Continued

Registration No.	Company No.	Product name	Active ingredients
2693–196	2693	VC17M with Biolux Copper Powder V900	Copper as elemental.
6836–124	6836	Glybrom RW–97.5	2,4-Imidazolidinedione, 1-bromo-3-chloro-5,5-dimethyl- & 1,3-Dibromo-5,5-dimethylhydantoin.
6836–329	6836	Lonzabac 12 Preservative	1,3-Propanediamine, N-(3-aminopropyl)-N-dodecyl-.
9150–11	9150	Cryocide 20	Chlorine dioxide & 1-Decanaminium, N-decyl-N,N-dimethyl-, chloride.
9150–15	9150	Anthium Pesticidal Disinfecting Spray	1-Decanaminium, N-decyl-N,N-dimethyl-, chloride & Chlorine dioxide
10324–99	10324	Maquat 10–PD	Alkyl* dimethyl benzyl ammonium chloride *(60%C14, 30%C16, 5%C18, 5%C12) & Alkyl* dimethyl ethylbenzyl ammonium chloride *(68%C12, 32%C14).
10324–142	10324	Maquat MQ2525M–14	Alkyl* dimethyl ethylbenzyl ammonium chloride *(68%C12, 32%C14) & Alkyl* dimethyl benzyl ammonium chloride *(60%C14, 30%C16, 5%C18, 5%C12).
52287–11	52287	Fertilizer with Starteem(R) #2	Trifluralin; Benfluralin & Oxadiazon.
59682–5	59682	Fast Attack	Nonylphenoxypolyethoxyethanol—iodine complex.
67799–3	67799	Sea Fresh 150	Sulfur dioxide.
70506–33	70506	Devrinol 2–G Ornamental Selective Herbicide	Napropamide.
70506–37	70506	Devrinol 3.75 SC Landscape and Nursery Selective Herbicide (Active); Devrinol 4–F Ornamental Selective Herbicide (Alternate).	Napropamide.
70506–38	70506	Devrinol 50–DF Ornamental Selective Herbicide	Napropamide.
70506–39	70506	Devrinol Lawn and Ornamental Selective Herbicide	Napropamide.
70506–63	70506	Devrinol 2–EC Ornamental Selective Herbicide	Napropamide.
70506–263	70506	Doubledown	Oxadiazon & Oxyfluorfen.
70506–373	70506	Dupont Londax G Herbicide	Bensulfuron-methyl.
87373–41	87373	A364.02	Paraquat dichloride.
87373–112	87373	Paraquat Technical	Paraquat dichloride.
91234–87	91234	A364.01	Paraquat dichloride.
IN–110004	62719	Instinct	Nitrapyrin.
IN–130001	10163	Malathion 8	Malathion (NO INERT USE).
IN–130002	10163	Malathion 8	Malathion (NO INERT USE).
KS–170001	100	Dual Magnum Herbicide	S-Metolachlor.
NJ–990006	62719	Confirm 2F Agricultural Insecticide	Tebufenozide.
OK–990002	62719	Confirm 2F Agricultural Insecticide	Tebufenozide.
OR–110018	59639	Valor Herbicide	Flumioxazin.
VA–980006	62719	RH–5992 2F Experimental Insecticide	Tebufenozide.
WA–110011	62719	Opensight	Metsulfuron & Aminopyralid-potassium.
WA–140004	62719	Entrust SC	Spinosad.
WA–140005	81880	GWN–1715	Pyridaben.
WA–170001	81880	Nexter SC Miticide/Insecticide	Pyridaben.

TABLE 2—PRODUCT REGISTRATION AMENDMENTS TO TERMINATE USES

Registration No.	Company No.	Product name	Active ingredient	Uses to be terminated
45728–21	45728	Thiram Granuflo Agricultural Fungicide.	Thiram	Turf and golf.
45728–26	45728	Thiram SC	Thiram	Turf and golf.
85678–67	85678	Bifenthrin 2E	Bifenthrin	Crop use for Nurseries.
94730–3	94730	Bifenthrin Technical	Bifenthrin	Indoor Residential.

Table 3 of this unit includes the names and addresses of record for all registrants of the products in Tables 1

and 2 of this unit, in sequence by EPA company number. This number corresponds to the first part of the EPA

registration numbers of the products listed above.

TABLE 3—REGISTRANTS OF CANCELLED AND AMENDED PRODUCTS

EPA company No.	Company name and address
100	Syngenta Crop Protection, LLC, 410 Swing Road, P.O. Box 18300, Greensboro, NC 27419–8300.
228	NuFarm Americas, Inc., 4020 Aerial Center Pkwy., Ste. 101, Morrisville, NC 27560.
1381	Winfield Solutions, LLC, P.O. Box 64589, St. Paul, MN 55164–0589.
2693	International Paint, LLC, 6001 Antoine Drive, Houston, TX 77091.
6836	Arxada, LLC, 412 Mount Kemble Avenue, Suite 200S, Morristown, NJ 07960.

TABLE 3—REGISTRANTS OF CANCELLED AND AMENDED PRODUCTS—Continued

EPA company No.	Company name and address
9150	International Dioxide, Inc., 40 Whitecap Drive, North Kingstown, RI 02852.
10163	Gowan Company, LLC, 370 S Main St., Yuma, AZ 85366.
10324	Mason Chemical Company, 9075 Centre Pointe Dr., Suite 400, West Chester, OH 45069.
45728	Taminco US, LLC, A Subsidiary of Eastman Chemical Company, c/o John Hott-B280, 200 S Wilcox Dr., Kingsport, TN 376605147.
52287	Harrell's, LLC, P.O. Box 807, Lakeland, FL 33802.
59639	Valent U.S.A. LLC, 4600 Norris Canyon Road, P.O. Box 5075, San Ramon, CA 94583.
59682	Controlled Release Technologies, Inc., 1016 Industry Drive, Shelby, NC 28152.
62719	Corteva Agriscience, LLC, 9330 Zionsville Road, Indianapolis, IN 46268.
67799	Seaco Technologies, Inc., P.O. Box 80205, Bakersfield, CA 93380.
70506	UPL NA, Inc., 630 Freedom Business Center, Suite 402, King of Prussia, PA 19406.
81880	Canyon Group, LLC, c/o Gowan Company, 370 S Main Street, Yuma, AZ 85364.
85678	RedEagle International, LLC, Agent Name: Wagner Regulatory Associates, Inc., 7217 Lancaster Pike, Suite A, P.O. Box 640, Hockessin, DE 19707.
87373	Argite, LLC, Agent Name: Pyxis Regulatory Consulting, Inc., 4110 136th Street Ct. NW, Gig Harbor, WA 98332.
91234	Atticus, LLC, Agent Name: Pyxis Regulatory Consulting, Inc., 4110 136th Street Ct. NW, Gig Harbor, WA 98332–9122.
94730	Generic Crop Science, LLC, Agent Name: Wagner Regulatory Associates, Inc., 7217 Lancaster Pike, Ste. A, P.O. Box 640 Hockessin, DE 19707.

III. Summary of Public Comments Received and Agency Response to Comments

During the public comment period provided, EPA received no comments in response to the August 29, 2022, **Federal Register** notice announcing the Agency's receipt of the requests for voluntary cancellations and amendments to terminate uses of products listed in Tables 1 and 2 of Unit II.

IV. Cancellation Order

Pursuant to FIFRA section 6(f) (7 U.S.C. 136d(f)(1)), EPA hereby approves the requested cancellations and amendments to terminate uses of product registrations identified in Tables 1 and 2 of Unit II. Accordingly, the Agency hereby orders that the product registrations identified in Tables 1 and 2 of Unit II, are canceled and amended to terminate the affected uses. The effective date of the cancellations that are subject of this notice is November 22, 2022. Any distribution, sale, or use of existing stocks of the products identified in Tables 1 and 2 of Unit II, in a manner inconsistent with any of the provisions for disposition of existing stocks set forth in Unit VI, will be a violation of FIFRA.

V. What is the Agency's authority for taking this action?

Section 6(f)(1) of FIFRA (7 U.S.C. 136d(f)(1)) provides that a registrant of a pesticide product may at any time request that any of its pesticide registrations be canceled or amended to

terminate one or more uses. FIFRA further provides that, before acting on the request, EPA must publish a notice of receipt of any such request in the **Federal Register**. Thereafter, following the public comment period, the EPA Administrator may approve such a request. The notice of receipt for this action was published for comment in the **Federal Register** of August 29, 2022 (87 FR 52773) (FRL–9997–01–OCSPP). The comment period closed on September 28, 2022.

VI. Provisions for Disposition of Existing Stocks

Existing stocks are those stocks of registered pesticide products which are currently in the United States, and which were packaged, labeled, and released for shipment prior to the effective date of the action. The existing stocks provision for the products subject to this order is as follows.

For 10324–142, listed in Table 1 of Unit II, the registrant has requested an 18-month sell-through period. The registrant may continue to sell and distribute existing stocks of 10324–142 until May 22, 2024, a period of 18 months after publication of the cancellation order in this **Federal Register**, unless other restrictions have been imposed. Thereafter, the registrant will be prohibited from selling or distributing the product.

For all other voluntary cancellations listed in Table 1 of Unit II, the registrants may continue to sell and distribute existing stocks of the products listed in Table 1 of Unit II, until November 22, 2023, which is 1 year after publication of this cancellation

order in the **Federal Register**.

Thereafter, the registrants are prohibited from selling or distributing all other products listed in Table 1 of Unit II, except for export in accordance with FIFRA section 17 (7 U.S.C. 136o) or for proper disposal.

Now that EPA has approved product labels reflecting the requested amendments to terminate uses listed in Table 2 of Unit II, registrants are permitted to sell or distribute products listed in Table 2 of Unit II, under the previously approved labeling until May 22, 2024, a period of 18 months after publication of the cancellation order in this **Federal Register**, unless other restrictions have been imposed. Thereafter, registrants will be prohibited from selling or distributing the products whose labels include the terminated uses identified in Table 2 of Unit II, except for export consistent with FIFRA section 17 or for proper disposal.

Persons other than the registrant may sell, distribute, or use existing stocks of canceled products and products whose labels include the terminated uses, until supplies are exhausted, provided that such sale, distribution, or use is consistent with the terms of the previously approved labeling on, or that accompanied, the canceled products and terminated uses.

Authority: 7 U.S.C. 136 *et seq.*

Dated: November 15, 2022.

Daniel Rosenblatt,

Acting Director, Registration Division, Office of Pesticide Programs.

[FR Doc. 2022–25344 Filed 11–21–22; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY**[FRL-10398-01-OA]****Request for Nominations for the Science Advisory Board Inorganic Arsenic Review Panel****AGENCY:** Environmental Protection Agency (EPA).**ACTION:** Notice.

SUMMARY: The Environmental Protection Agency (EPA) Science Advisory Board (SAB) Staff Office requests public nominations of scientific experts to form a Panel to review the draft EPA Integrated Risk Information System (IRIS) Toxicological Review of Inorganic Arsenic. Based on the publicly available systematic review protocol, EPA's draft assessment includes a summary of the chemical properties and pharmacokinetics; hazard identification analysis for diseases of the circulatory system, pregnancy and birth outcomes, diabetes, and neurodevelopmental effects; and dose-response analysis characterizing the quantitative relationship for the noncancer outcomes listed above as well as for bladder cancer and lung cancer. These quantitative relationships are then used to derive cancer and non-cancer toxicity values (e.g., oral slope factor, reference dose). The SAB Inorganic Arsenic Review Panel will consider whether the conclusions found in the EPA's draft assessment are clearly presented and scientifically supported.

DATES: Nominations should be submitted by December 9, 2022 per the instructions below.

FOR FURTHER INFORMATION CONTACT: Any member of the public wishing further information regarding this Notice and Request for Nominations may contact Dr. Diana Wong, Designated Federal Officer (DFO), EPA Science Advisory Board Staff Office by telephone/voice mail (202) 564-2049, or email at wong.diana-m@epa.gov. General information concerning the EPA SAB can be found at the EPA SAB website at <https://sab.epa.gov>.

SUPPLEMENTARY INFORMATION:

Background: The SAB (42 U.S.C. 4365) is a chartered Federal Advisory Committee that provides independent scientific and technical peer review, advice, and recommendations to the EPA Administrator on the technical basis for EPA actions. As a Federal Advisory Committee, the SAB conducts business in accordance with the Federal Advisory Committee Act (FACA) (5 U.S.C. app. 2) and related regulations. The SAB Staff Office is forming an

expert panel, the SAB Inorganic Arsenic Review Panel, under the auspices of the Chartered SAB. The SAB Inorganic Arsenic Review Panel will provide advice through the chartered SAB. The SAB and the Inorganic Arsenic Review Panel will comply with the provisions of FACA and all appropriate SAB Staff Office procedural policies.

The SAB Inorganic Arsenic Review Panel will conduct a review of the draft EPA IRIS Toxicological Review of Inorganic Arsenic. Based on the publicly available systematic review protocol, EPA's draft assessment includes a summary of the chemical properties and pharmacokinetics; hazard identification analysis for diseases of the circulatory system, pregnancy and birth outcomes, diabetes, and neurodevelopmental effects; and dose-response analysis characterizing the quantitative relationship for the noncancer outcomes listed above as well as for bladder cancer and lung cancer. The SAB Inorganic Arsenic Review Panel will consider whether the conclusions found in the EPA's draft assessment are clearly presented and scientifically supported. The Panel will also be asked to provide recommendations on how the assessment may be strengthened.

Request for Nominations: The SAB Staff Office is seeking nominations of nationally and internationally recognized scientists with demonstrated expertise and experience in the following disciplines: Epidemiology, including specific expertise in carcinogenesis, cardiovascular disease, reproductive and developmental toxicity, neurodevelopmental outcomes, and diabetes; systematic review; physiologically-based pharmacokinetic (PBPK) modeling; risk assessment; epidemiological dose-response analysis; and Bayesian statistics.

Process and Deadline for Submitting Nominations: Any interested person or organization may nominate qualified individuals in the areas of expertise described above for possible service on the SAB Panel. Individuals may self-nominate. Nominations should be submitted in electronic format (preferred) using the online nomination form on the SAB website at <https://sab.epa.gov> (see the "Public Input on Membership" list under "Committees, Panels, and Membership"). To be considered, nominations should include the information requested below. EPA values and welcomes diversity. All qualified candidates are encouraged to apply regardless of sex, race, disability or ethnicity. Nominations should be submitted in time to arrive no later than December 9, 2022. The following

information should be provided on the nomination form: contact information for the person making the nomination; contact information for the nominee; and the disciplinary and specific areas of expertise of the nominee. Nominees will be contacted by the SAB Staff Office and will be asked to provide a recent curriculum vitae and a narrative biographical summary that includes current position; educational background; research activities; sources of research funding for the last two years; and recent service on other national advisory committees or national professional organizations. Persons having questions about the nomination procedures, or who are unable to submit nominations through the SAB website, should contact the DFO at the contact information noted above. The names and biosketches of qualified nominees identified by respondents to this **Federal Register** notice, and additional experts identified by the SAB Staff Office, will be posted in a List of Candidates for the Panel on the SAB website at <https://sab.epa.gov>. Public comments on the List of Candidates will be accepted for 21 days. The public will be requested to provide relevant information or other documentation on nominees that the SAB Staff Office should consider in evaluating candidates.

For the EPA SAB Staff Office, a balanced review panel includes candidates who possess the necessary domains of knowledge, the relevant scientific perspectives (which, among other factors, can be influenced by work history and affiliation), and the collective breadth of experience to adequately address the charge. In forming the expert panel, the SAB Staff Office will consider public comments on the Lists of Candidates, information provided by the candidates themselves, and background information independently gathered by the SAB Staff Office. Selection criteria to be used for panel membership include: (a) scientific and/or technical expertise, knowledge, and experience (primary factors); (b) availability and willingness to serve; (c) absence of financial conflicts of interest; (d) absence of an appearance of a loss of impartiality; (e) skills working in committees, subcommittees and advisory panels; and (f) for the panel as a whole, diversity of expertise and scientific points of view.

The SAB Staff Office's evaluation of an absence of financial conflicts of interest will include a review of the "Confidential Financial Disclosure Form for Environmental Protection Agency Special Government Employees" (EPA Form 3110-48). This

confidential form is required and allows government officials to determine whether there is a statutory conflict between a person's public responsibilities (which include membership on an EPA federal advisory committee) and private interests and activities, or the appearance of a loss of impartiality, as defined by federal regulation. The form may be viewed and downloaded through the "Ethics Requirements for Advisors" link on the SAB website at <https://sab.epa.gov>. This form should not be submitted as part of a nomination.

V. Khanna Johnston,

Deputy Director, Science Advisory Board Staff Office.

[FR Doc. 2022-25170 Filed 11-21-22; 8:45 am]

BILLING CODE 6560-50-P

FEDERAL ELECTION COMMISSION

Sunshine Act Meeting

FEDERAL REGISTER CITATION NOTICE OF PREVIOUS ANNOUNCEMENT: 87 FR 69271.

PREVIOUSLY ANNOUNCED TIME, DATE, AND PLACE OF THE MEETING: Thursday, November 17, 2022 at 10:00 a.m.

Hybrid meeting: 1050 First Street NE, Washington, DC (12th Floor) and virtual.

CHANGES IN THE MEETING: The Open Meeting of Thursday, November 17, 2022 was canceled.

CONTACT PERSON FOR MORE INFORMATION: Judith Ingram, Press Officer, Telephone: (202) 694-1220.

(Authority: Government in the Sunshine Act, 5 U.S.C. 552b)

Laura E. Sinram,

Secretary and Clerk of the Commission.

[FR Doc. 2022-25536 Filed 11-18-22; 11:15 am]

BILLING CODE 6715-01-P

GULF COAST ECOSYSTEM RESTORATION COUNCIL

[Docket No. 111162022-111-01]

Senior Executive Service Performance Review Board Membership

AGENCY: Gulf Coast Ecosystem Restoration Council (GCERC).

ACTION: Notice of Performance Review Board (PRB) appointments.

SUMMARY: This notice announces the members of the Senior Executive Service (SES) Performance Review Board. The PRB is comprised of a Chairperson and a mix of state representatives and career senior

executives that meet annually to review and evaluate performance appraisal documents and provide a written recommendation to the Chairperson of the Council for final approval of each executive's performance rating, performance-based pay adjustment, and performance award.

DATES: The board membership is applicable beginning on 12/01/2021 and ending on 12/31/22.

FOR FURTHER INFORMATION CONTACT: Mary S. Walker, Executive Director, Gulf Coast Ecosystem Restoration Council, telephone 504-210-9982.

SUPPLEMENTARY INFORMATION: In accordance with 5 U.S.C. 4314(c)(4), the persons named below have been selected to serve on the PRB:

Department of Commerce

Carrie Robinson, National Oceanic and Atmospheric Administration, National Marine Fisheries Service, Office of the Habitat Conservation and Restoration, Carrie.Robinson@noaa.gov, 301-427-8605

State of Louisiana

Chris Barnes, Coastal Protection and Restoration Authority, Legal Advisor, Coastal Activities, Chris.Barnes@la.gov, 225-342-9036

State of Mississippi

Wells, Chris, Executive Director, Mississippi Department of Environmental Quality, cwells@mdeq.ms.gov, 601-961-5545

Environmental Protection Agency

Wyatt, Marc, Director, Gulf of Mexico Division, Wyatt.marc@epa.gov, 228-679-5915

Keala Hughes,

Director of External Affairs and Tribal Relations.

[FR Doc. 2022-25360 Filed 11-21-22; 8:45 am]

BILLING CODE 6560-58-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[60Day-23-23AX; Docket No. CDC-2022-0132]

Proposed Data Collection Submitted for Public Comment and Recommendations

AGENCY: Centers for Disease Control and Prevention (CDC), Department of Health and Human Services (HHS).

ACTION: Notice with comment period.

SUMMARY: The Centers for Disease Control and Prevention (CDC), within the Department of Health and Human Services, as part of its continuing effort to reduce public burden and maximize the utility of government information, invites the general public and other federal agencies the opportunity to comment on a proposed information collection, as required by the Paperwork Reduction Act of 1995. This notice invites comment on a proposed information collection project titled Assessing Knowledge, Attitudes, and Practices (KAPs) of Hispanic/Latina Women of Reproductive Age about Folic Acid Fortification and Supplementation. The data collection will involve focus groups of Hispanic/Latina populations to understand knowledge, awareness, and practices about use of folic acid and fortified food for neural tube defect (NTD) prevention.

DATES: CDC must receive written comments on or before January 23, 2023.

ADDRESSES: You may submit comments, identified by Docket No. CDC-2022-0132 by either of the following methods:

- *Federal eRulemaking Portal:* www.regulations.gov. Follow the instructions for submitting comments.
- *Mail:* Jeffrey M. Zirger, Information Collection Review Office, Centers for Disease Control and Prevention, 1600 Clifton Road NE, MS H21-8, Atlanta, Georgia 30329.

Instructions: All submissions received must include the agency name and Docket Number. CDC will post, without change, all relevant comments to www.regulations.gov.

Please note: Submit all comments through the Federal eRulemaking portal (www.regulations.gov) or by U.S. mail to the address listed above.

FOR FURTHER INFORMATION CONTACT: To request more information on the proposed project or to obtain a copy of the information collection plan and instruments, contact Jeffrey M. Zirger, Information Collection Review Office, Centers for Disease Control and Prevention, 1600 Clifton Road NE, MS H21-8, Atlanta, Georgia 30329; Telephone: 404-639-7570; Email: omb@cdc.gov.

SUPPLEMENTARY INFORMATION: Under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501-3520), federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. In addition, the PRA also requires federal agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each new

proposed collection, each proposed extension of an existing collection of information, and each reinstatement of a previously approved information collection before submitting the collection to the OMB for approval. To comply with this requirement, we are publishing this notice of a proposed data collection as described below.

The OMB is particularly interested in comments that will help:

1. Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;
2. Evaluate the accuracy of the agency’s estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;
3. Enhance the quality, utility, and clarity of the information to be collected;
4. Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, e.g., permitting electronic submissions of responses; and
5. Assess information collection costs.

Proposed Project

Assessing Knowledge, Attitudes, and Practices (KAPs) of Hispanic/Latina

Women of Reproductive Age (WRA) about Folic Acid Fortification and Supplementation—New—National Center on Birth Defects and Developmental Disabilities (NCBDDD), Centers for Disease Control and Prevention (CDC).

Background and Brief Description

A contemporary understanding of cultural factors in the decision-making process and how certain populations of women obtain information is needed for Hispanic/Latina women of reproductive age (WRA) to increase their knowledge and intake of folic acid to prevent neural tube defects (NTD).

Previous research highlighted important nuances in potential cultural beliefs regarding folic acid. A study of Spanish-speaking, Hispanic/Latina women in the southwest United States found no cultural barriers to incorporating folic-acid rich foods into their diets; however, focus groups of Mexican-American women within the study found several cultural barriers. These included: misperception of the term folic acid as an illegal substance (as the word “acid” is sometimes used to describe the drug LSD); the importance of folic acid in preventing NTDs since their healthcare providers did not talk to them about folic acid; the absence of folic acid in injectable form at the pharmacy; and mistaken beliefs that birth defects are not preventable (resulting from an act of God). Other

studies also present contradictory findings suggesting that Spanish-speaking, Mexican-American women have increased awareness of the association between folate and birth defects compared to English-speaking, Mexican-American women. Although several studies have examined beliefs and best practices for promoting folic acid consumption, more research is needed to determine cultural factors in the decision-making process around folic acid intake for Hispanic/Latina WRA.

The objective of this project is to conduct formative research with Hispanic/Latina WRA and leadership from key organizations that serve Hispanic/Latina populations to understand the following: (1) knowledge and awareness about folic acid and fortified food for NTD prevention; (2) practices around consumption of fortified foods as well as traditional food items that may or may not be fortified and supplement use; and (3) appropriate messages and dissemination channels to improve folic acid intake from supplements and folic acid fortified foods among Hispanic/Latina WRA.

This information collection will involve focus groups with Hispanic/Latina WRA. CDC requests OMB approval for an estimated 63 annual burden hours. There are no costs to respondents other than their time to participate.

ESTIMATED ANNUALIZED BURDEN HOURS

Type of respondents	Form name	Number of respondents	Number of responses per respondent	Average burden per response (in hours)	Total burden (in hours)
Hispanic/Latina Women of Reproductive Age (WRA)	Knowledge, Attitudes, and Practices (KAPs) of Hispanic/Latina WRA: Focus Group Moderator Guide.	63	1	1	63
Total	63

Jeffrey M. Zirger,
Lead, Information Collection Review Office,
Office of Scientific Integrity, Office of Science,
Centers for Disease Control and Prevention.
[FR Doc. 2022–25400 Filed 11–21–22; 8:45 am]
BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[Docket No. CDC–2022–0116]

CDC Recommendations for Hepatitis C Testing Among Perinatally Exposed Infants and Children—United States, 2023; Request for Comment and Notice of Informational Webinar

AGENCY: Centers for Disease Control and Prevention (CDC), Department of Health and Human Services (HHS).

ACTION: Notice with comment.

SUMMARY: The Centers for Disease Control and Prevention (CDC), in the Department of Health and Human Services (HHS), announces the opening of a docket to obtain comment on proposed new recommendations for perinatal hepatitis C virus (HCV) infection testing to identify infants who may go on to develop chronic hepatitis C. Recommendations include: HCV testing of all perinatally exposed infants at age 2–6 months with a Nucleic Acid Test (NAT) for detection of HCV ribonucleic acid (RNA); and referral of infants with detectable HCV RNA to a healthcare provider with expertise in pediatric hepatitis C management. CDC

also announces an Informational Webinar to explain the public comment process.

DATES: Written comments must be received on or before January 27, 2023.

The Informational Webinar will be held December 6, 2022 from 3–4 p.m. EST.

ADDRESSES: You may submit comments, identified by Docket No. CDC–2022–0116 by either of the methods listed below.

- **Federal eRulemaking Portal:** <https://www.regulations.gov>. Follow the instructions for submitting comments.

- **Mail:** Division of Viral Hepatitis, Centers for Disease Control and Prevention, 1600 Clifton Road NE, Mailstop U12–3, Atlanta, GA 30329, Attn: Docket No. CDC–2022–0116.

Instructions: All submissions received must include the agency name and Docket Number. All relevant comments received will be posted without change to <https://www.regulations.gov>, including any personal information provided. Do not submit comments by email; CDC does not accept comments by email. For access to the docket to read background documents or comments received, go to <https://www.regulations.gov>.

Registration for Informational Webinar: You can register for the webinar at https://www.zoomgov.com/webinar/register/WN_tDK5btj3QpGcmDzKvJvDbw. CDC will not accept public comment during this webinar.

FOR FURTHER INFORMATION CONTACT: Lakshmi Panagiotakopoulos, Centers for Disease Control and Prevention, 1600 Clifton Road NE, Mailstop U12–3, Atlanta, GA 30329. Email: DVHpolicy@cdc.gov. Telephone: (404) 639–8000.

SUPPLEMENTARY INFORMATION:

Background

Hepatitis C virus (HCV) infection is the most commonly reported blood-borne infection in the United States, causing substantial liver damage and death.¹ During 2017–2020, there were

an estimated 2.2 million non-institutionalized adults in the United States living with hepatitis C.² Percutaneous exposure (*e.g.*, injection drug use or blood transfusion) is the most efficient mode of HCV transmission, and injection drug use is the primary risk factor for infection.³ National surveillance data reveal a steady increase in HCV infections in the United States from 2010 through 2020, with rates of acute infections more than quadrupling among reproductive aged persons during this time, corresponding with increases in injection drug use.⁴ Approximately 7 percent of perinatally exposed children (*i.e.*, those coming into contact with the virus during pregnancy or delivery) will acquire perinatal HCV infection.⁵ Curative direct-acting antiviral (DAA) drugs are an FDA-approved treatment, currently approved for use beginning at 3 years of age. However, many perinatally infected children are not tested or linked to care.^{6,7,8,9}

The World Health Organization (WHO)'s global health sector strategies¹⁰ for eliminating viral hepatitis include diagnosing at least 90% of people living with hepatitis C by 2030. In support of this goal, CDC conducted a systematic review of the literature to develop recommendations

² Thompson WW, Symum H, Sandul A, et al. Vital Signs: Hepatitis C Treatment Among Insured Adults—United States, 2019–2020. *MMWR Morb Mortal Wkly Rep* 2022;71:1011–1017. DOI: <http://dx.doi.org/10.15585/mmwr.mm7132e1>.

³ Centers for Disease Control and Prevention. Viral Hepatitis Surveillance Report—United States, 2020. <https://www.cdc.gov/hepatitis/statistics/2020surveillance/index.htm>. Published September 2022.

⁴ Centers for Disease Control and Prevention. Viral Hepatitis Surveillance Report—United States, 2020. <https://www.cdc.gov/hepatitis/statistics/2020surveillance/index.htm>. Published September 2022.

⁵ Benova, L., et al., Vertical transmission of hepatitis C virus: systematic review and meta-analysis. *Clin Infect Dis*, 2014. 59(6): p. 765–73.

⁶ Towers, C.V. and K.B. Fortner. Infant follow-up postdelivery from a hepatitis C viral load positive mother. *J Matern Fetal Neonatal Med*, 2019. 32(19): p. 3303–3305.

⁷ Lopata, S.M., et al., Hepatitis C Testing Among Perinatally Exposed Infants. *Pediatrics*, 2020. 145(3).

⁸ Hojat, L.S., et al., Using Preventive Health Alerts in the Electronic Health Record Improves Hepatitis C Virus Testing Among Infants Perinatally Exposed to Hepatitis C. *Pediatr Infect Dis J*, 2020. 39(10): p. 920–924.

⁹ Kuncio, D.E., et al., Failure to Test and Identify Perinatally Infected Children Born to Hepatitis C Virus-Infected Women. *Clin Infect Dis*, 2016. 62(8): p. 980–5.

¹⁰ Global health sector strategies on, respectively, HIV, viral hepatitis and sexually transmitted infections for the period 2022–2030. Geneva: World Health Organization; 2022. License: CC BY–NC–SA 3.0 IGO. Available at: <https://www.who.int/teams/global-hiv-hepatitis-and-stis-programmes/strategies/global-health-sector-strategies>.

for testing perinatally exposed infants and children for hepatitis C. Among children born to women with HCV infection, well-child visits in the first 6 months of life are the most frequently attended and provide an opportunity to test in a patient group that is often lost to follow-up. Although treatment is not currently approved for infants and children under 3 years of age, it is important to test exposed infants as close to birth as possible and record a diagnosis in the medical record. HCV-infected infants and children are usually asymptomatic, and it is important to diagnose and treat HCV infection before liver damage occurs. Prior studies have estimated that, in the United States, the total annual burden of HCV infection was about 10 billion U.S. dollars in 2017.¹¹ Proper identification of perinatally infected children, referral to care for evaluation and monitoring, and curative DAA treatment are critical to achieving the goal of hepatitis C elimination.

As described in the recommendation document found in the Supporting and Related Materials tab of the docket, these recommendations supplement “CDC Recommendations for Hepatitis C Screening Among Adults—United States, 2020,” which includes screening during each pregnancy, by recommending the timing and type of HCV test for infants and children born to persons determined to have HCV infection in pregnancy. In addition, this recommendation replaces a prior recommendation for testing perinatally exposed infants and children included in a CDC guideline from 1998,¹² as HCV epidemiology and methods of testing infants and children for HCV infection have evolved.

Public Participation

Interested persons or organizations are invited to participate by submitting written views, recommendations, and data related to any of the proposed recommendations or supporting evidence. In addition, CDC invites comments specifically on the following questions:

- Based on the evidence presented in the full recommendations document (*see* Supporting and Related Materials tab), does the evidence support the proposed recommendations for testing

¹¹ Stepanova M, Younossi ZM. Economic Burden of Hepatitis C Infection. *Clin Liver Dis*. 2017 Aug;21(3):579–594. doi: 10.1016/j.cld.2017.03.012. Epub 2017 Apr 22. PMID: 28689595.

¹² Recommendations for prevention and control of hepatitis C virus (HCV) infection and HCV-related chronic disease. Centers for Disease Control and Prevention. *MMWR Recomm Rep*. 1998 Oct 16;47(RR–19):1–39. PMID: 9790221.

¹ Centers for Disease Control and Prevention. Viral Hepatitis Surveillance Report—United States, 2020. <https://www.cdc.gov/hepatitis/statistics/2020surveillance/index.htm>. Published September 2022. *See also* Hofmeister, M.G., Rosenthal, E.M., Barker, L.K., Rosenberg, E.S., Barranco, M.A., Hall, E.W., Edlin, B.R., Mermin, J., Ward, J.W. and Ryerson, A.B. (2019). Estimating Prevalence of Hepatitis C Virus Infection in the United States, 2013–2016. *Hepatology*, 69: 1020–1031. <https://doi.org/10.1002/hep.30297> Rosenberg ES, Rosenthal EM, Hall EW, Barker L, Hofmeister MG, Sullivan PS, Dietz P, Mermin J, Ryerson AB. Prevalence of Hepatitis C Virus Infection in US States and the District of Columbia, 2013 to 2016. *JAMA Netw Open*. 2018 Dec 7;1(8):e186371. doi: 10.1001/jamanetworkopen.2018.6371. PMID: 30646319; PMCID: PMC6324373.

perinatally exposed infants and children for HCV infection? If not, please state the reason why and, if available, provide additional evidence for consideration.

- Are CDC's proposed recommendations (*see* Supporting and Related Materials tab) clearly written? If not, please provide changes to make them clearer.

- If implemented as currently drafted, do you believe the proposed recommendations would result in increased identification and treatment of perinatal HCV infections and reduction in associated health and financial consequences in the United States (*e.g.*, healthcare costs to treat complications of chronic hepatitis C)? If not, please provide an explanation.

Please note that comments received, including attachments and other supporting materials, are part of the public record and are subject to public disclosure. Comments will be posted on <https://www.regulations.gov>. Therefore, do not include any information in your comment or supporting materials that you consider confidential or inappropriate for public disclosure. If you include your name, contact information, or other information that identifies you in the body of your comments, that information will be on public display. CDC will review all submissions and may choose to redact or withhold submissions containing private or proprietary information such as Social Security numbers, medical information, inappropriate language, or duplicate or near duplicate examples of a mass-mail campaign.

Informational Webinar: CDC will host an Informational Webinar on December 6, 2022 from 3:00–4:00 p.m. EST to explain the public comment process. CDC will not accept public comment on the Draft Recommendations during the webinar.

Dated: November 17, 2022.

Angela K. Oliver,

Executive Secretary, Centers for Disease Control and Prevention.

[FR Doc. 2022–25421 Filed 11–21–22; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Submission for OMB Review; Annual Report on Households Assisted by the Low Income Home Energy Assistance Program (OMB #0970–0060)

AGENCY: Office of Community Services (OCS), Administration for Children and Families (ACF), Department of Health and Human Services (HHS).

ACTION: Request for public comment.

SUMMARY: OCS, Division of Energy Assistance, is requesting a substantial change of the Household Report Office of Management and Budget (OMB) #0970–0060, expiration May 31, 2025). Grant recipients complete the Household Report on an annual basis, completing either the Long Form or the Short Form version of the report. Submission of the completed report is one requirement for the Low Income Home Energy Assistance Program (LIHEAP) grant recipients applying for Federal LIHEAP block grant funds. OCS proposes substantive changes, including the addition of reporting requirements for assisted applicants and household member demographic characteristics on the Household Report Long Form and Short Form, and the removal of reporting requirements collecting counts of applicant households by assistance type and poverty interval on the Household Report Long Form.

DATES: *Comments due within 30 days of publication.* OMB must make a decision about the collection of information between 30 and 60 days after publication of this document in the **Federal Register**. Therefore, a comment is best assured of having its full effect if OMB receives it within 30 days of publication.

ADDRESSES: Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to www.reginfo.gov/public/do/PRAMain. One can find this particular information collection by selecting “Currently under 30-day Review-Open for Public Comments” or by using the search function. You can also obtain copies of the proposed collection of information by emailing infocollection@acf.hhs.gov. Identify all emailed requests by the title of the information collection.

SUPPLEMENTARY INFORMATION:

Description: States, the District of Columbia, and the Commonwealth of Puerto Rico are required to complete the

Household Report-Long Form on an annual basis. The Long Form collects the following information:

- Assisted households, by type of LIHEAP assistance and funding source;
- Assisted households receiving bill payment assistance, by funding source;
- Assisted households receiving any type of LIHEAP assistance, by funding source;
- Assisted households by poverty interval, type of LIHEAP assistance, and funding source;
- Assisted households, by type of LIHEAP assistance and funding source, having at least one vulnerable member who is at least 60 years or older, disabled, or 5 years old or younger;
- Assisted households receiving any type of LIHEAP assistance or funding source, having at least one member 60 years or older, disabled, or 5 years old or younger.

Tribal grant recipients and other U.S. territory grant recipients are required to complete the Household Report-Short Form on an annual basis. The Short Form collects data only on the number of households, by funding source, receiving heating, cooling, energy crisis, and/or weatherization benefits.

The information reported in the Household Report Long Form and Short Form is being collected for the Department's annual LIHEAP Report to Congress. The data also provides information about the need for LIHEAP funds. Finally, the data are used in the calculation of LIHEAP performance measures under the Government Performance and Results Act of 1993. The data elements will allow the accuracy of measuring LIHEAP targeting performance and LIHEAP cost efficiency.

ACF is proposing changes to the Household Report Long Form and Short Form beginning with FY 2023 reporting. These changes include additional reporting requirements for assisted household and household member demographic characteristics, and the removal of reporting requirements collecting counts of applicant households by assistance type and poverty interval on the Household Report Long Form. The additional reporting requirements include the following:

1. Number of Households by Owner/Renter Status (own, rent with utilities billed separately, rent with utilities in rental fee, other) [This is optional for FY 2023 reporting and required beginning with FY 2024 reporting].

2. Number of Assisted Applicants by Ethnicity. Grant recipients will report on assisted applicants by ethnicity according to standard census categories

[This is required beginning with FY 2023 reporting].

3. Number of Assisted Applicants by Race. Grant recipients will report on assisted applicants by race according to standard census categories [This is required beginning with FY 2023 reporting].

4. Number of Assisted Applicants by Gender. Grant recipients will report on assisted applicants by gender [This is required beginning with FY 2023 reporting].

5. Number of Assisted Household Members by Ethnicity. Grant recipients will report on assisted household members by ethnicity according to standard census categories [This is optional for FY 2023 reporting and required beginning with FY 2024 reporting].

6. Number of Assisted Household Members by Race. Grant recipients will report on assisted household members by race according to standard census categories [This is optional for FY 2023

reporting and required beginning with FY 2024 reporting].

7. Number of Assisted Household Members by Gender. Grant recipients will report on assisted household members by gender [This is optional for FY 2023 reporting and required beginning with FY 2024 reporting].

The proposed additions will provide OCS with critical data that is needed to evaluate if LIHEAP is equitably serving communities across the country. The collection of demographic data including owner/renter status, race, ethnicity, and gender will allow OCS to conduct analysis disaggregated by these variables to assess whether the LIHEAP resources are equity distributed. Therefore, this data collection aligns with the goals of Executive Order 13985 (Advancing Racial Equity and Support for Underserved Communities Through the Federal Government). Additionally, collecting demographic data in LIHEAP will bring the program into alignment

with other programs across OCS including the Community Services Block Grant, which currently collects demographic data on beneficiaries, and Low Income Household Water Assistance Program (LIHWAP), which will collect demographic data on beneficiaries in FY 2023.

To minimize reporting burden to the greatest extent possible, and in recognition of the significant overlap in LIHEAP and LIHWAP grant recipients, OCS is proposing to use the same demographic measures included in the LIHWAP Annual Report in the LIHEAP Household Report. OCS has also removed the reporting requirements for applicant households by assistance type and poverty interval on the Household Report Long Form to offset some of the additional reporting burden entailed by the demographic data collection.

Respondents: State governments, tribal governments, U.S. territories, and the District of Columbia

ANNUAL BURDEN ESTIMATES

Instrument	Total number of respondents	Total number of responses per respondent	Average burden hours per response	Annual burden hours
Assisted Household Report-Long Form	56	1	67	3,752
Assisted Household Report-Short Form	151	1	10	1,510
Household Application	6,160,000	1	1	6,160,000

Estimated Total Annual Burden Hours: 6,165,262.

Please note that the above estimate accounts for the burden this data collection entails on LIHEAP applicants. In previous years, OCS has not included an estimate of the burden on households. While OCS does not mandate that LIHEAP grant recipients use a standard household application, we know that grant recipients collect many of the required Household Report data elements through their household application. The annual burden for the household application indicated above accounts for the time it will take LIHEAP applicants to provide the data required by the current Household Report as well as the proposed demographic data elements. To calculate this burden, we used an estimate for the annual number of LIHEAP household applicants multiplied by an average of an hour to provide the data required by the Household Report.

Authority: U.S.C. 8629 and 45 CFR.

Mary B. Jones,
ACF/OPRE Certifying Officer.

[FR Doc. 2022–25336 Filed 11–21–22; 8:45 am]

BILLING CODE 4184–80–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Statement of Organization, Functions, and Delegations of Authority; Correction

AGENCY: Office of Regulatory Affairs, Food and Drug Administration, Department of Health and Human Services.

ACTION: Notice; correction.

SUMMARY: The Food and Drug Administration (FDA) is correcting a notice entitled “Statement of Organization, Functions, and Delegations of Authority” that appeared in the **Federal Register** of September 28, 2022. The document announced the publication of a reorganization of the Office of Regulatory Affairs (ORA)

headquarters and field offices. This **Federal Register** notice (FRN) contained editorial errors. The FRN did not accurately list ORA’s new organization. The corrections depict the proper organizational components within ORA.

FOR FURTHER INFORMATION CONTACT:

Glenda Barfell, Associate Commissioner for Regulatory Management Operations, Office of Regulatory Management Operations, Office of Regulatory Affairs, Food and Drug Administration, Element Building, Rm. 2002, 12420 Parklawn Dr., Rockville, MD 20857, 240–402–7562.

SUPPLEMENTARY INFORMATION:

In the **Federal Register** of Wednesday, September 28, 2022 (87 FR 58807), appearing on pages 58807 through 58810 in FR Doc. 2022–20996, the following corrections are made:

1. On page 58807, in the second column, “Data Analytics and Program Evaluation Staff (DCIA1)” is corrected to read “Data Analytics and Program Evaluation Staff (DCIA2).”

2. On page 58807, in the second column, “Division of Facilities and Property Management (DCIBBBB)” is

corrected to read “Division of Facilities and Property Management (DCIBBB).”

3. On page 58807, in the second column, “Laboratory Support Branch (DCIBBBB1)” is corrected to read “Laboratory Support Branch (DCIBBB1).”

4. On page 58807, in the third column, “Medical Products Travel Branch (DCIBBD2)” is corrected to read “Medical Products Foreign Travel Branch (DCIBBD2).”

5. On page 58807, in the third column, “Human and Animal Food Travel Branch (DCIBBD3)” is corrected to read “Human and Animal Food Foreign Travel Branch (DCIBBD3).”

6. On page 58808, in the first column, “Project Management Branch 1 (DCIDB1)” is corrected to read “Project Management Branch 1 (DCIDB2).”

7. On page 58808, in the first column, “Project Management Branch 2 (DCIDB2)” is corrected to read “Project Management Branch 2 (DCIDB3).”

8. On page 58808, in the first column, “Foreign Human and Animal Food Inspections Branch 1 (DCIEBA)” is corrected to read “Foreign Human and Animal Food Inspections Branch 1 (DCIEBA1).”

9. On page 58808, in the second column, “Human and Animal Food Investigations Branch 2 (DCIECF2)” is corrected to read “Human and Animal Food Compliance Branch (DCIECF2).”

10. On page 58808, in the second column, “Human and Animal Food Compliance Branch (DCIECF3)” is corrected to read “Human and Animal Food Investigations Branch 2 (DCIECF3).”

11. On page 58808, in the third column, “Chemistry Branch (DCIFCD1)” is corrected to read “Chemistry Branch (DCIFCD2).”

12. On page 58808, in the third column, “Microbiological Sciences Branch (DCIFCD2)” is corrected to read “Microbiological Sciences Branch (DCIFCD3).”

13. On page 58809, in the first column, “Bioresearch Monitoring Operations Staff (DCIGA1)” is corrected to read “Operations Staff (DCIGA1).”

14. On page 58809, in the first column, “Operations Staff (DCIGA2)” is corrected to read “Bioresearch Monitoring Dedicated Foreign Cadre Staff (DCIGA2).”

15. On page 58809, in the first column, “Bioresearch Monitoring Dedicated Foreign Cadre Staff (DCIGA3)” is removed.

16. On page 58809, in the second column, “Division of Information Disclosure Policy (DCIHBD)” is corrected to read “Division of Information Disclosure (DCIHBD).”

17. On page 58809, in the third column, “Disclosure Policy Branch (DCIHBD3)” is corrected to read “Disclosure Branch (DCIHBD3).”

18. On page 58809, in the third column, “Produce Branch (DCIHBD4)” is corrected to read “Produce Branch (DCIHA3).”

19. On page 58809, in the third column, “Imports Policy Branch (DCIHEA3)” and “Division of Planning and Evaluation (DCIHEB)” are removed.

20. On page 58809, in the third column, “Division of Enforcement (DCIHEC)” is corrected to read “Division of Compliance and Enforcement (DCIHEC).”

21. On page 58809, in the third column, “Recall Operations Branch (DCIHEC1)” is corrected to read “Recalls Branch (DCIHEC1).”

22. On page 58809, in the third column, “Northern Boarder Import Investigations Branch I (DCIIH1)” is corrected to read “Northern Border Import Investigations Branch I (DCIIH1).”

23. On page 58809, in the third column, “Northern Boarder Import Investigations Branch II (DCIIH2)” is corrected to read “Northern Border Import Investigations Branch II (DCIIH2).”

24. On page 58809, in the third column, “Northern Boarder Import Compliance Branch (DCIIH3)” is corrected to read “Northern Border Import Compliance Branch (DCIIH3).”

25. On page 58809, in the third column, “Office of Information Systems Management (DCIJ)” is corrected to read “Office of Information Systems Management (DCIK).”

26. On page 58809, in the third column, “Division of Enforcement Systems Solutions (DCIJA)” is corrected to read “Division of Enforcement Systems Solutions (DCIKA).”

27. On page 58809, in the third column, “Enforcement Systems Branch (DCIJA1)” is corrected to read “Enforcement Systems Branch (DCIKA1).”

28. On page 58810, in the first column, “Enforcement Data Management Branch (DCIJA2)” is corrected to read “Enforcement Data Management Branch (DCIKA2).”

29. On page 58810, in the first column, “Division of Import Systems Solutions (DCIJB)” is corrected to read “Division of Import Systems Solutions (DCIKB).”

30. On page 58810, in the first column, “Import Systems Branch (DCIJB1)” is corrected to read “Import Systems Branch (DCIKB1).”

31. On page 58810, in the first column, “Import Data Management

Branch (DCIJB2)” is corrected to read “Import Data Management Branch (DCIKB2).”

32. On page 58810, in the first column, “Division of Information Technology Planning and Management Services (DCIJC)” is corrected to read “Division of Information Technology Planning and Management Services (DCIKC).”

33. On page 58810, in the first column, “Solutions Planning Branch (DCIJC1)” is corrected to read “Solutions Planning Branch (DCIKC1).”

34. On page 58810, in the first column, “Information Technology Management and Governance Services Branch (DCIJC2)” is corrected to read “Information Technology Management and Governance Services Branch (DCIKC2).”

Elizabeth J. Gramling,

*Executive Secretary to the Department,
Department of Health and Human Services.*

[FR Doc. 2022–25409 Filed 11–21–22; 8:45 am]

BILLING CODE P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2022–N–2841]

Science Board to the Food and Drug Administration Advisory Committee; Notice of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) announces a forthcoming public advisory committee meeting of the Science Board to the Food and Drug Administration (Science Board). The Science Board provides advice to the Commissioner of Food and Drugs and other appropriate officials on specific, complex scientific and technical issues important to FDA and its mission, including emerging issues within the scientific community. Additionally, the Science Board provides advice to the Agency on keeping pace with technical and scientific developments, including in regulatory science, input into the Agency’s research agenda, and on upgrading its scientific and research facilities and training opportunities. It will also provide, where requested, expert review of Agency-sponsored intramural and extramural scientific research programs. The meeting will be open to the public.

DATES: The meeting will be held virtually on December 8, 2022, from 9 a.m. to 4 p.m. Eastern Time.

ADDRESSES: Please note that due to the impact of this COVID-19 pandemic, all meeting participants will be joining this advisory committee meeting via an online teleconferencing platform. Answers to commonly asked questions about FDA advisory committee meetings may be accessed at: <https://www.fda.gov/AdvisoryCommittees/AboutAdvisoryCommittees/ucm408555.htm>.

FOR FURTHER INFORMATION CONTACT:

Rakesh Raghuvanshi, Office of the Chief Scientist, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 1, Rm. 3309, Silver Spring, MD 20993, 301-796-4769, rakesh.raghuvanshi@fda.hhs.gov, or FDA Advisory Committee Information Line, 1-800-741-8138 (301-443-0572 in the Washington, DC area). A notice in the **Federal Register** about last minute modifications that impact a previously announced advisory committee meeting cannot always be published quickly enough to provide timely notice. Therefore, you should always check the Agency's website at <https://www.fda.gov/AdvisoryCommittees/default.htm> and scroll down to the appropriate advisory committee meeting link, or call the advisory committee information line to learn about possible modifications before coming to the meeting.

SUPPLEMENTARY INFORMATION:

Agenda: The meeting presentations will be heard, viewed, captioned, and recorded through an online teleconferencing platform. The Science Board will consider research needs for the evaluation of potential adverse health effects in children associated with oral cadmium exposure. The Science Board will also hear about the Agency's cross-cutting regulatory science research activities and its recent Focus Areas of Regulatory Science report.

FDA intends to make background material available to the public no later than 2 business days before the meeting. If FDA is unable to post the background material on its website prior to the meeting, the background material will be made publicly available on FDA's website at the time of the advisory committee meeting. Background material and the link to the online teleconference meeting room will be available at <https://www.fda.gov/AdvisoryCommittees/Calendar/default.htm>. Scroll down to the appropriate advisory committee meeting link. The meeting will include slide

presentations with audio components to allow the presentation of materials in a manner that most closely resembles an in-person advisory committee meeting.

Procedure: Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Written submissions may be made to the contact person on or before December 2, 2022. Oral presentations from the public will be scheduled between approximately 11 a.m. and 12 p.m. Those individuals interested in making formal oral presentations should notify the contact person and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation on or before December 1, 2022. Time allotted for each presentation may be limited. If the number of registrants requesting to speak is greater than can be reasonably accommodated during the scheduled open public hearing session, FDA may conduct a lottery to determine the speakers for the scheduled open public hearing session. The contact person will notify interested persons regarding their request to speak by December 2, 2022.

For press inquiries, please contact the Office of Media Affairs at fdaoma@fda.hhs.gov or 301-796-4540.

FDA welcomes the attendance of the public at its advisory committee meetings and will make every effort to accommodate persons with disabilities. If you require accommodations due to a disability, please contact Rakesh Raghuvanshi (see **FOR FURTHER INFORMATION CONTACT**) at least 7 days in advance of the meeting.

FDA is committed to the orderly conduct of its advisory committee meetings. Please visit our website at <https://www.fda.gov/AdvisoryCommittees/AboutAdvisoryCommittees/ucm111462.htm> for procedures on public conduct during advisory committee meetings.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).

Dated: November 16, 2022.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2022-25405 Filed 11-21-22; 8:45 am]

BILLING CODE 4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2022-N-2657]

Agency Information Collection Activities; Proposed Collection; Comment Request; Food and Drug Administration's Study of Assessing Physiological, Neural and Self-Reported Response to Tobacco Education Messages

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing an opportunity for public comment on the proposed collection of certain information by the Agency. Under the Paperwork Reduction Act of 1995 (PRA), Federal Agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information and to allow 60 days for public comment in response to the notice. This notice solicits comments on FDA's investigation of how youth and young adults process tobacco education messaging and to identify effective tobacco prevention and education message strategies.

DATES: Either electronic or written comments on the collection of information must be submitted by January 23, 2023.

ADDRESSES: You may submit comments as follows. Please note that late, untimely filed comments will not be considered. The <https://www.regulations.gov> electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of January 23, 2023. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are received on or before that date.

Electronic Submissions

Submit electronic comments in the following way:

- **Federal eRulemaking Portal:** <https://www.regulations.gov>. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to <https://www.regulations.gov> will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or

anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on <https://www.regulations.gov>.

- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see "Written/Paper Submissions" and "Instructions").

Written/Paper Submissions

Submit written/paper submissions as follows:

- *Mail/Hand Delivery/Courier (for written/paper submissions):* Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in "Instructions."

Instructions: All submissions received must include the Docket No. FDA-2022-N-2657 for "Food and Drug Administration's Study of Assessing Physiological, Neural and Self-Reported Response to Tobacco Education Messages." Received comments, those filed in a timely manner (see **ADDRESSES**), will be placed in the docket and, except for those submitted as "Confidential Submissions," publicly viewable at <https://www.regulations.gov> or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday, 240-402-7500.

- **Confidential Submissions**—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states "THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION." The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on <https://www.regulations.gov>. Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this

information on the cover sheet and not in the body of your comments and you must identify this information as "confidential." Any information marked as "confidential" will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: <https://www.govinfo.gov/content/pkg/FR-2015-09-18/pdf/2015-23389.pdf>.

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to <https://www.regulations.gov> and insert the docket number, found in brackets in the heading of this document, into the "Search" box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 240-402-7500.

FOR FURTHER INFORMATION CONTACT:

JonnaLynn Capezzuto, Office of Operations, Food and Drug Administration, Three White Flint North, 10A-12M, 11601 Landsdown St., North Bethesda, MD 20852, 301-796-3794, PRAStaff@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: Under the PRA (44 U.S.C. 3501-3521), Federal Agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. "Collection of information" is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes Agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal Agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on these topics: (1) whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the

collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

Food and Drug Administration's Study of Assessing Physiological, Neural and Self-Reported Response to Tobacco Education Messages

OMB Control Number 0910-NEW

On June 22, 2009, the President signed the Family Smoking Prevention and Tobacco Control Act (Tobacco Control Act) (Pub. L. 111-31) into law. The Tobacco Control Act granted FDA authority to regulate the manufacture, marketing, and distribution of tobacco products; to inform the public on health-related issues; and to protect public health by reducing tobacco use and by preventing death and disease caused by tobacco use.

FDA's Center for Tobacco Products (CTP) was created to carry out the authorities granted under the Tobacco Control Act, to educate the public about the dangers of tobacco use and serve as a public health resource for tobacco and health information. Through CTP, FDA researches, develops, and distributes information about tobacco and health to the public, professionals, various branches of government, and other interested groups nationwide using a wide array of formats and media channels. FDA's "The Real Cost" campaign (<https://www.fda.gov/tobacco-products/public-health-education-campaigns/real-cost-campaign>) uses evidence-based paid media advertising to highlight the negative health consequences of tobacco use. To develop the appropriate messaging to inform the public, it is important for FDA to conduct research to assess youth and young adults' perceptions of tobacco use prevention messaging.

The study of "Assessing Physiological, Neural and Self-Reported Response to Tobacco Education Messages" is voluntary research. Information obtained through this study will primarily be used to assess the performance of ads developed to reduce tobacco initiation and use among at-risk youth and young adults as part of CTP's "The Real Cost" campaign. Traditionally, message testing research employs self-reported measures of perceived effectiveness (e.g., an individual's perception that the ad would make one less likely to use tobacco), but research indicates that while these self-reported measures are useful, they may be imperfect proxies for real world knowledge, attitude, and behavior change. This imprecision

could lead message developers to select less than optimal messages or cost-ineffective strategies for widespread dissemination.

Physiological and neural responses to tobacco education messages offer an innovative and useful supplement to traditional self-report measures. Indicators such as heart rate variability, galvanic skin response, and facial electromyography can assess arousal and affective response to messages, while tools such as eye tracking and neuroimaging can measure attention and levels of activation in key areas in the brain associated with message processing and message acceptance. Research indicates that these techniques can be more effective than self-report measures at predicting “real world” tobacco education message effectiveness.

There is a need for research that implements these techniques to identify the most effective tobacco prevention and education message strategies. Additionally, there is a need to triangulate data collected through physiological and neuroimaging-based approaches with self-reported measures to better understand how self-reported measures can be implemented in order to accurately predict knowledge, attitude, and behavior change.

This study will recruit participants from the Baltimore, Maryland area to participate in an in-person study visit at Johns Hopkins University Bloomberg School of Public Health. Inclusion and exclusion criteria are based on the target populations for “The Real Cost” campaign. Specifically, the study will collect data from two groups: 50 youth (aged 13–17) and 50 young adults (aged 18–24 years old). Participants will be stratified by electronic nicotine delivery systems and cigarette use, so that approximately half of each sample will

be: (1) at risk for initiating a tobacco product (*i.e.*, think they might try one in the near future or would try one if a friend offered it to them) or (2) tobacco experimenter (have had at least 1 but less than 100 cigarettes in their lifetime; have had at least 1 puff of an e-cigarette). Individuals who respond that they have never used tobacco products and respond “definitely not” to all questions assessing openness to tobacco use will be excluded from participation. Additionally, those who have established tobacco use patterns will be excluded from participation. Both groups are outside the target demographic for “The Real Cost” campaign.

The study will use community-based recruiting, using methods such as flyers posted at locations frequented by young adults, teenagers, and their parents (*e.g.*, local Baltimore City colleges, markets, and other relevant venues), social media, and word-of-mouth. Flyers will be posted with permission and advertise the study as assessing perceptions of tobacco education messages using monitors placed on the head, face, and fingers; special glasses; and a survey. Participants will be directed to complete an online screening survey before scheduling their study visit.

For youth participants, eligible participants will provide contact information for their parent/guardian. The study team will then contact the parent and receive parental permission and schedule a study visit. At the study visit, study personnel will confirm that 13–15-year-olds are accompanied by someone 18 or older, and then the youth will provide assent. For young adult participants, after completing the screener, eligible participants will provide their contact information. The study team will then contact the participant and schedule a study visit.

At the study visit, young adult participants will provide informed consent prior to beginning study participation.

After the consenting/assenting process, participants will complete one study visit (90 minutes long) in which they will view four FDA tobacco education and prevention ads. First, participants will complete a survey and be fitted with neuroimaging and psychophysiological equipment. Second, participants will be fitted for a functional near-infrared spectroscopy (fNIRS) headband (the headband can be adjusted based on head circumference) and then have the fNIRS headband and electrodes for physiological data collection, and eye-tracking glasses placed on them. They will then complete a series of computer tasks to ensure placement of the fNIRS headband and fill out part one of the survey on demographic characteristics, tobacco use behaviors, and social influence related to tobacco use. Next, they will view tobacco education messages, and complete part two of the survey providing self-reported response data (*e.g.*, how much they liked the ad) after each message. Participants will conclude the survey by completing the third part of the survey assessing psychosocial variables. Participants will receive a small incentive as a token of appreciation in exchange for their survey participation. Additionally, for youth (ages 13–15) participants, the adult who accompanies the youth will receive a token of appreciation in exchange for costs of accompanying the youth to the study site (*e.g.*, parking, gas, and potential loss of income/childcare needed for youth to participate).

FDA estimates the burden of this collection of information as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN ¹

Participant subgroup	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours ¹
Number to take the eligibility screener					
Youth (aged 13–17)	150	1	150	0.083 (5 minutes)	13
Young adults (aged 18–24)	150	1	150	0.083 (5 minutes)	13
Total					26
Number to obtain parental permission process (for parents of youth only) and schedule site visit					
Parents of youth participants	75	1	75	0.167 (10 minutes)	13
Young adults (aged 18–24)	50	1	50	0.083 (5 minutes)	4
Total					17

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN ¹—Continued

Participant subgroup	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours ¹
Number to complete consent (5 min) and main study (85 min)					
Youth (aged 13–17)	50	1	50	1.5	75
Young adults (aged 18–24)	50	1	50	1.5	75
Total	150
Total	193

¹ There are no capital costs or operating and maintenance costs associated with this collection of information.

FDA's burden estimate is based on prior experience with research that is similar to this proposed study. Applying assumptions from previous experience in conducting similar studies, approximately 150 youth and 150 young adults would take the eligibility screener, which is estimated to take 5 minutes to read and respond. An estimated 75 parents of youth participants will provide parental permission and schedule a site visit (10 minutes total); and an estimated 50 young adults will schedule a site visit (5 minutes). Finally, approximately 50 youth and 50 young adults will complete an in-person study visit that consists of the consent/assent (5 minutes) and complete the main study (85 minutes) to yield the desired sample size of 100 total. The total estimated burden for the data collection is 193 hours. Table 1 details these estimates.

Dated: November 16, 2022.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2022–25406 Filed 11–21–22; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Solicitation of Nominations for Membership To Serve on the Advisory Committee on Infant and Maternal Mortality

AGENCY: Health Resources and Services Administration (HRSA), Department of Health and Human Services (HHS).

ACTION: Request for nominations.

SUMMARY: HRSA is seeking nominations of qualified candidates for consideration for appointment as members of the Advisory Committee on Infant and Maternal Mortality (ACIMM or Committee). ACIMM advises the Secretary of HHS (Secretary) on

department activities, partnerships, policies, and programs directed at reducing infant mortality, maternal mortality and severe maternal morbidity, and improving the health status of infants and women before, during, and after pregnancy. HRSA is seeking nominations of qualified candidates to fill open positions on the ACIMM.

DATES: Written nominations for membership on the ACIMM must be received on or before January 23, 2023.

ADDRESSES: Nomination packages must be submitted electronically as email attachments to Vanessa Lee, MPH, the ACIMM's Designated Federal Official, at: SACIM@hrsa.gov.

FOR FURTHER INFORMATION CONTACT: Vanessa Lee, MPH, Designated Federal Official, Maternal and Child Health Bureau, HRSA, 5600 Fishers Lane, Room 18N84, Rockville, Maryland 20857; 301–443–0543; or SACIM@hrsa.gov. A copy of the ACIMM charter and list of the current membership may be obtained by accessing the ACIMM website at <https://www.hrsa.gov/advisory-committees/infant-mortality/index.html>.

SUPPLEMENTARY INFORMATION: The ACIMM was established in 1991 and advises the Secretary on department activities, partnerships, policies, and programs directed at reducing infant mortality, maternal mortality and severe maternal morbidity, and improving the health status of infants and women before, during, and after pregnancy. The Committee provides advice on how to coordinate federal, state, local, tribal, and territorial governmental efforts designed to improve infant mortality, related adverse birth outcomes, and maternal health, as well as influence similar efforts in the private and voluntary sectors. The Committee provides guidance and recommendations on the policies, programs, and resources required to address the disparities and inequities in infant mortality, related adverse birth

outcomes and maternal health outcomes, including maternal mortality and severe maternal morbidity. With its focus on underlying causes of the disparities and inequities seen in birth outcomes for women and infants, the Committee advises the Secretary on the health, social, economic, and environmental factors contributing to the inequities and proposes structural, policy, and/or systems level changes. The ACIMM shall meet approximately four times per year, or at the discretion of the Designated Federal Officer in consultation with the Chair.

Nominations: HRSA is requesting nominations for voting members to serve as Special Government Employees (SGEs) on the ACIMM to fill open positions. The Secretary appoints ACIMM members with the expertise needed to fulfill the duties of the Advisory Committee. Information about SGE membership on the ACIMM is set forth in the ACIMM charter. Nominees sought are medical, technical, or scientific professionals with special expertise in the field of maternal and child health, in particular infant and/or maternal mortality and related health disparities; members of the public having special expertise about or concern with infant and/or maternal mortality; and/or representatives from such public health constituencies, consumers, and medical professional societies. Interested applicants may self-nominate or be nominated by another individual or organization.

ACIMM consists of up to 21 members appointed by the Secretary for a term of up to 4 years. Individuals selected for appointment to the Committee will be invited to serve for up to 4 years. Members appointed as SGEs receive a stipend and reimbursement for per diem and travel expenses incurred for attending ACIMM meetings and/or conducting other business on behalf of the ACIMM, as authorized by 5 U.S.C. 5703 for persons employed intermittently in government service.

The following information must be included in the package of materials submitted for each individual nominated for consideration: (1) A statement that includes the name and affiliation of the nominee and a clear statement regarding the basis for the nomination, including the area(s) of expertise and/or experience that may qualify a nominee for service on the ACIMM, as described above; (2) confirmation the nominee is willing to serve as a member of the ACIMM; (3) the nominee's contact information (please include home address, work address, daytime telephone number, and an email address); and (4) a current copy of the nominee's curriculum vitae or resume. Nomination packages may be submitted directly by the individual being nominated or by the person/organization recommending the candidate.

HHS endeavors to ensure that the membership of the ACIMM is fairly balanced in terms of points of view represented and that individuals from a broad representation of geographic areas, gender, and ethnic and minority groups, as well as individuals with disabilities, are considered for membership. Appointments shall be made without discrimination on the basis of age, ethnicity, gender, sexual orientation, or cultural, religious, or socioeconomic status.

Individuals who are selected to be considered for appointment will be required to provide detailed information regarding their financial holdings, consultancies, and research grants or contracts. Disclosure of this information is required in order for HRSA ethics officials to determine whether there is a potential conflict of interest between the SGE's public duties as a member of the ACIMM and their private interests, including an appearance of a loss of impartiality as defined by federal laws and regulations, and to identify any required remedial action needed to address the potential conflict.

Authority: ACIMM is authorized by section 222 of the Public Health Service Act (42 U.S.C. 217a), as amended. The Committee is governed by provisions of Public Law 92-463, as amended, (5 U.S.C. app. 2).

Maria G. Button,

Director, Executive Secretariat.

[FR Doc. 2022-25435 Filed 11-21-22; 8:45 am]

BILLING CODE 4165-15-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Agency Information Collection Activities: Proposed Collection: Public Comment Request Information Collection Request Title: Ryan White HIV/AIDS Program: Allocations Forms, OMB No. 0915-0318—Revision

AGENCY: Health Resources and Services Administration (HRSA), Department of Health and Human Services.

ACTION: Notice.

SUMMARY: In compliance with the requirement for opportunity for public comment on proposed data collection projects of the Paperwork Reduction Act of 1995, HRSA announces plans to submit an Information Collection Request (ICR), described below, to the Office of Management and Budget (OMB). Prior to submitting the ICR to OMB, HRSA seeks comments from the public regarding the burden estimate, below, or any other aspect of the ICR.

DATES: Comments on this ICR should be received no later than January 23, 2023.

ADDRESSES: Submit your comments to paperwork@hrsa.gov or mail the HRSA Information Collection Clearance Officer, Room 14N39, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: To request more information on the proposed project or to obtain a copy of the data collection plans and draft instruments, mail paperwork@hrsa.gov or call Samantha Miller, the acting HRSA Information Collection Clearance Officer, at (301) 443-9094.

SUPPLEMENTARY INFORMATION: When submitting comments or requesting information, please include the information request collection title for reference.

Information Collection Request Title: Ryan White HIV/AIDS Program: Allocations Forms, OMB No. 0915-0318—Revision.

Abstract: HRSA's HIV/AIDS Bureau administers the Ryan White HIV/AIDS Program (RWHAP) authorized under Title XXVI of the Public Health Service Act as amended by the Ryan White HIV/AIDS Treatment Extension Act of 2009. The RWHAP Allocations and Expenditures Reports (A&E Reports) allow HRSA to monitor and track the use of grant funds for compliance with program and grants policies, and requirements as outlined in the legislation. To avoid duplication and reduce recipient reporting burden, HRSA created an electronic grantee

contract management system (GCMS) that includes data required for various reports, including the Allocations Reports and other HRSA data reports, such as the RWHAP Services Report. Recipients can access GCMS year-round to upload or manually enter data on their service provider contractors or subrecipients, the RWHAP core medical and support services provided, and their funding amounts. Data required for Allocations Reports and other reports are automatically prepopulated from GCMS. Expenditures Report data are not auto-populated in the GCMS, and are thus still manually entered into the data reporting system.

Allocations and Expenditures (A&E) Reports

Recipients funded under RWHAP Parts A, B, C, and D are required to report financial data to HRSA at the beginning (Allocations Report) and at the end of their grant budget period (Expenditures Report). The A&E Reports request information recipients already collect, including the use of RWHAP grant funds for core medical and support services; and on various program components, such as administration, planning and evaluation, and clinical quality management. RWHAP Parts A and B recipients funded under the Ending the HIV Epidemic Initiative (EHE) are also required to report EHE services allocations and corresponding EHE award expenditures in the A&E Reports. This allows HRSA to track and report progress toward meeting the EHE goals. The reports are similar in content; however, in the first report, recipients document the allocation of their RWHAP grant award at the beginning of their grant budget period. In the second report, recipients document actual expenditures of their RWHAP grant award (including any carryover dollars) at the end of their grant budget period.

HRSA is proposing the following updates to the RWHAP Allocation Reports.

RWHAP Part A Allocations Report

- Revising row and column headers and other language for clarity and alignment with RWHAP requirements;
- Combining the columns for RWHAP Part A Formula and Supplemental Allocation amounts and updating the title;
- Moving the RWHAP Part A Minority AIDS Initiative (MAI) Award Amount row after the RWHAP Part A Supplemental Award Amount row;
- Changing the calculation for Service Allocation Subtotal percent in the Total

RWHAP Part A Allocation Amounts column;

- Blacking out the percent columns for the RWHAP Part A Formula and Supplemental Allocation Amounts, RWHAP Part A MAI Allocation Amounts, and selected cells in the Total RWHAP Part A Allocation Amounts column; and

- Adding the Legislative Requirements Checklist.

RWHAP Part B Allocations Report

- Revising row and column headers and other language for clarity and alignment with RWHAP requirements;

- Adding the following rows to Table 1: 4c. Part B HIV Care Consortia Planning & Evaluation/Emerging Communities (EC) HIV Care Consortia Planning & Evaluation and 4d. Part B HIV Care Consortia Clinical Quality Management (CQM)/EC HIV Care Consortia CQM except for the AIDS Drug Assistance Program (ADAP) Earmark + ADAP Supplemental Award cells;

- Removing row 11. Total Part B X07 Allocations;

- Allowing users to enter data in Table 2 for 1d. Health Insurance Premium & Cost Sharing and 1e. Home and Community-based Health Services;

- Blacking out selected cells in the following rows, columns, or tables:

- 2. Part B Health Insurance Premium & Cost Sharing Assistance for Low-Income Individuals (Table 1) as this information is also reported in Table 2

- 3. Part B Home and Community-based Health Services (Table 1) as this information is also reported in Table 2

- 4. Total Column (Table 1)

- 1a. AIDS Drug Assistance Program Treatments (Table 2) as this information is also reported in Table 1

- MAI Award (Table 3); and

- Updating calculations and language in the Legislative Requirements Checklist.

RWHAP Part C Allocations Report

- There are no proposed changes to the RWHAP Part C Allocations Report.

RWHAP Part D Allocations Report

- There are no proposed changes to the RWHAP Part D Allocations Report.

HRSA EHE A&E Reports

- There are no proposed changes to the HRSA EHE Allocations Reports.

Need and Proposed Use of the

Information: Accurate allocation, expenditure, and service contract records of the recipients receiving RWHAP funding are critical to the implementation of the RWHAP legislation and thus are necessary for HRSA to fulfill its monitoring and oversight responsibilities.

Likely Respondents: RWHAP Part A, Part B, Part C, and Part D recipients.

Burden Statement: Burden in this context means the time expended by persons to generate, maintain, retain, disclose, or provide the information requested. This includes the time needed to review instructions; to develop, acquire, install, and utilize technology and systems for the purpose of collecting, validating and verifying information, processing and maintaining information, and disclosing and providing information; to train personnel and to be able to respond to a collection of information; to search data sources; to complete and review the collection of information; and to transmit or otherwise disclose the information. The total annual burden hours estimated for this ICR are summarized in the table below.

TOTAL ESTIMATED ANNUALIZED BURDEN HOURS

Form name	Number of respondents	Number of responses per respondent	Total responses	Average burden per response (in hours)	Total burden hours
Part A Allocations Report	52	1	52	4	208
Part B Allocations Report	54	1	54	6	324
Part C Allocations Report	346	1	346	4	1,384
Part D Allocations Report	116	1	116	4	464
EHE Allocations Reports	47	1	47	4	188
Total	615	615	2,568

HRSA specifically requests comments on (1) the necessity and utility of the proposed information collection for the proper performance of the agency's functions, (2) the accuracy of the estimated burden, (3) ways to enhance the quality, utility, and clarity of the information to be collected, and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

Maria G. Button,

Director, Executive Secretariat.

[FR Doc. 2022-25449 Filed 11-21-22; 8:45 am]

BILLING CODE 4165-15-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Committee on Vital and Health Statistics; Meeting

AGENCY: Centers for Disease Control and Prevention, HHS.

ACTION: Notice of meeting.

SUMMARY: Pursuant to the Federal Advisory Committee Act, the Department of Health and Human Services (HHS) announces the following advisory committee meeting. This meeting is open to the public. The public is welcome to obtain the link to attend this meeting by following the instructions posted on the Committee website: <https://ncvhs.hhs.gov/meetings/full-committee-meeting-12/>.

DATES: The meeting will be held Tuesday, December 6, 2022: 10:30 a.m.–5:30 p.m. EDT and Wednesday, December 7, 2022: 10:30 a.m.–4:30 p.m. EDT.

ADDRESSES: Virtual open meeting.

FOR FURTHER INFORMATION CONTACT:

Substantive program information may be obtained from Rebecca Hines, MHS, Executive Secretary, NCVHS, National Center for Health Statistics, Centers for Disease Control and Prevention, 3311 Toledo Road, Hyattsville, Maryland 20782, via electronic mail to vgh4@cdc.gov; or by telephone (301) 458-4715. Summaries of meetings and a roster of Committee members are available on the home page of the NCVHS website <https://ncvhs.hhs.gov/>, where further information including an

agenda and instructions to access the broadcast of the meeting will be posted.

Should you require reasonable accommodation, please telephone the CDC Office of Equal Employment Opportunity at (770) 488-3210 as soon as possible.

SUPPLEMENTARY INFORMATION:

Purpose: As outlined in its Charter, the National Committee on Vital and Health Statistics assists and advises the Secretary of HHS on health data, data standards, statistics, privacy, national health information policy, and the Department's strategy to best address those issues. At this meeting, the Committee will receive updates from HHS officials, hold discussions on current health data policy topics, and discuss its work plan for the upcoming period. The Subcommittee on Privacy, Confidentiality and Security (PCS) will present a recent environmental scan it commissioned entitled, "Ongoing and Emerging Issues in Privacy and Security in a Post-COVID-19 Era," and discuss with fellow members potential opportunities where the Committee's advice to HHS may be useful. The PCS Subcommittee also will review with the full Committee possible development of recommendations stemming from briefings held during the Committee's July 21, 2022, meeting specific to data access and privacy for Tribal Epidemiology Centers.

The Subcommittee on Standards will brief the Committee on preparations for its January 18–19, 2023, hearing focused on requests for new and updated transaction standards and operating rules. See the notice and request for comment regarding this meeting published at 87 **Federal Register** 65782 on November 1, 2022, and available at this link: <https://www.govinfo.gov/content/pkg/FR-2022-11-01/pdf/2022-23678.pdf>. The briefing will include an update on collaborations with the Workgroup on Electronic Data Interchange (WEDI)—also an advisor to the Secretary of Health and Human Services (HHS)—to inform deliberations as the Committee considers drafting recommendations to HHS on proposed

new and updated standards and operating rules. The Subcommittee on Standards also will update the full Committee on follow up activities to previous recommendations on the transition to the 11th Revision of the International Classification of Diseases (ICD-11) and discuss plans for the year ahead. Last, the Committee will identify areas of focus for its 2023 Report to Congress.

The Committee will reserve time for public comment toward the end of the agenda on both days. Meeting times and topics are subject to change. Please refer to the agenda posted on the NCVHS website for updates: <https://ncvhs.hhs.gov/meetings/full-committee-meeting-12/>.

Sharon Arnold,

Associate Deputy Assistant Secretary, Science and Data Policy, Office of the Assistant Secretary for Planning and Evaluation.

[FR Doc. 2022-25334 Filed 11-21-22; 8:45 am]

BILLING CODE 4150-05-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

[Document Identifier: OS-0990-New]

Agency Information Collection Request; 60-Day Public Comment Request

AGENCY: Office of the Secretary, HHS.

ACTION: Notice.

SUMMARY: In compliance with the requirement of the Paperwork Reduction Act of 1995, the Office of the Secretary (OS), Department of Health and Human Services, is publishing the following summary of a proposed collection for public comment.

DATES: Comments on the ICR must be received on or before January 23, 2023.

ADDRESSES: Submit your comments to Sherrette.Funn@hhs.gov or by calling (202) 264-0041.

FOR FURTHER INFORMATION CONTACT:

When submitting comments or requesting information, please include the document identifier 0990-New-60D

and project title for reference, to Sherrette A. Funn, email: Sherrette.Funn@hhs.gov, or call (202) 264-0041 the Reports Clearance Officer.

SUPPLEMENTARY INFORMATION: Interested persons are invited to send comments regarding this burden estimate or any other aspect of this collection of information, including any of the following subjects: (1) The necessity and utility of the proposed information collection for the proper performance of the agency's functions; (2) the accuracy of the estimated burden; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

Title of the Collection: Confidentiality of Substance Use Disorder Patient Records—42 CFR part 2 (formerly titled Confidentiality of Alcohol and Drug Abuse Patient Records—42 CFR part 2).

Type of Collection: Extension.

OMB No.: 0930-0092.

Abstract: The Substance Abuse and Mental Health Services Administration (SAMHSA) (through the Office for Civil Rights (OCR) requests approval to extend this existing, approved collection without changing any collecting requirements. OCR also expects to obtain public comment through a Notice of Proposed Rulemaking (NPRM) proposing modifications to 42 CFR part 2 that will affect the hourly burdens associated with the regulations. When the NPRM is published, we expect to receive robust public comment on existing burdens associated with compliance with the part 2 regulation and on changes in burden that could result from the modifications proposed in the NPRM. OCR will update this ICR to reflect the input we receive on this notice and through the rulemaking process.

Likely Respondents: Part 2 programs, qualified service organizations, patients with substance use disorders, and professional and trade associations of SUD treatment providers.

ANNUALIZED BURDEN HOUR TABLE

42 CFR	Annual number respondents (SUD programs)	Responses per respondent	Total responses (number of Tx admissions)	Hours per response	Total hour burden
§ 2.22	13,585	122.1	1,658,729	0.20	331,746
§§ 2.31, 2.52, and 2.53	13,585	18.31	248,741	0.62	155,463
§ 2.36	13,585	195.8	2,659,943	0.033	87,778
§ 2.51	13,585	2	27,170	0.167	4,537
Total	13,585	4,594,583	579,524

Carlos Graham,

Reports Clearance Officer.

[FR Doc. 2022–25343 Filed 11–21–22; 8:45 am]

BILLING CODE 4162–20–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Office of the Director, National Institutes of Health; Notice of Meeting

Pursuant to section 10(a) of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meetings of the Advisory Committee to the Director, National Institutes of Health.

The meetings will be open to the public as indicated below, with attendance limited to space available. Individuals who plan to attend as well as those who need special assistance, such as sign language interpretation or other reasonable accommodations, should notify the Contact Person listed below in advance of the meeting. The meeting sessions will be videocast and can be accessed from the NIH Videocasting website (<http://videocast.nih.gov/>).

Name of Committee: Advisory Committee to the Director, National Institutes of Health.

Date: December 8, 2022.

Time: 9:00 a.m. to 5:15 p.m.

Agenda: Performing the Duties of the NIH Director's Report; Updates on ARPA-H and COVID-19; Perspectives on the Current Cooperation with NIH and Priorities for the Future; Proposed Changes to Peer Review Criteria; ACD Working Group Updates; Other Business of the Committee.

Date: December 9, 2022.

Time: 9:00 a.m. to 3:15 p.m.

Agenda: HeLA Genome Data Access Requests; NIH RECOVER Initiative; NIH Efforts in Support of Open Data; Diversity, Equity, Inclusion and Accessibility (DEIA) Strategic Plan; ACD Working Group Updates; Update on UNITE; Other Business of the Committee.

Place: National Institutes of Health, Building 1, Wilson Hall, One Center Drive, Bethesda, MD 20892.

Contact Person: Cyndi Burrus-Shaw, Staff Assistant, National Institutes of Health, Office of the Director, One Center Drive, Building 1, Room 126, Bethesda, MD 20892, 301–496–2433, shawcy@od.nih.gov.

Any interested person may file written comments with the committee by forwarding the statement to the Contact Person listed on this notice. The statement should include the name, address, telephone number and when applicable, the business or professional affiliation of the interested person.

In the interest of security, NIH has procedures at <https://www.nih.gov/about-nih/visitor-information/campus-access-security> for entrance into on-campus and off-campus facilities. All visitor vehicles,

including taxicabs, hotel, and airport shuttles will be inspected before being allowed on campus. Visitors attending a meeting on campus or at an off-campus federal facility will be asked to show one form of identification (for example, a government-issued photo ID, driver's license, or passport) and to state the purpose of their visit.

Additional Health and Safety Guidance: Before attending a meeting at an NIH facility, it is important that visitors review the NIH COVID-19 Safety Plan at <https://ors.od.nih.gov/sr/dohs/safety/NIH-covid-19-safety-plan/Pages/default.aspx> for information about requirements and procedures for entering NIH facilities, especially when COVID-19 community levels are medium or high. In addition, the Safer Federal Workforce website has FAQs for visitors at <https://www.saferfederalworkforce.gov/faq/visitors/>. Please note that if an individual has a COVID-19 diagnosis within 10 days of the meeting, that person must attend virtually. (For more information please read NIH's Requirements for Persons after Exposure at <https://ors.od.nih.gov/sr/dohs/safety/NIH-covid-19-safety-plan/COVID-assessment-testing/Pages/persons-after-exposure.aspx> and What Happens When Someone Tests Positive at <https://ors.od.nih.gov/sr/dohs/safety/NIH-covid-19-safety-plan/COVID-assessment-testing/Pages/test-positive.aspx>.) Anyone from the public can attend the open portion of the meeting virtually via the NIH Videocasting website (<http://videocast.nih.gov>). Please continue checking these websites, in addition to the committee website listed below, for the most up to date guidance as the meeting date approaches.

Information is also available on the Institute's/Center's home page: <http://acd.od.nih.gov>, where an agenda and any additional information for the meeting will be posted when available.

(Catalogue of Federal Domestic Assistance Program Nos. 93.14, Intramural Research Training Award; 93.22, Clinical Research Loan Repayment Program for Individuals from Disadvantaged Backgrounds; 93.232, Loan Repayment Program for Research Generally; 93.39, Academic Research Enhancement Award; 93.936, NIH Acquired Immunodeficiency Syndrome Research Loan Repayment Program; 93.187, Undergraduate Scholarship Program for Individuals from Disadvantaged Backgrounds, National Institutes of Health, HHS)

Dated: November 16, 2022.

David W. Freeman,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2022–25389 Filed 11–21–22; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Allergy and Infectious Diseases; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: Microbiology, Infectious Diseases and AIDS Initial Review Group Acquired Immunodeficiency Syndrome Research Study Section Acquired Immunodeficiency Syndrome Research Study Section (AIDS).

Date: December 15, 2022.

Time: 10:00 a.m. to 5:30 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institute of Allergy and Infectious Diseases, National Institutes of Health, 5601 Fishers Lane, Room 3G21, Rockville, MD 20892 (Virtual Meeting).

Contact Person: Robert C. Unfer, Ph.D., Scientific Review Officer, Scientific Review Program, Division of Extramural Activities, National Institute of Allergy and Infectious Diseases, National Institutes of Health, 5601 Fishers Lane, Room 3G21, Bethesda, MD 20852, (240) 669–5035, robert.unfer@nih.gov. (Catalogue of Federal Domestic Assistance Program Nos. 93.855, Allergy, Immunology, and Transplantation Research; 93.856, Microbiology and Infectious Diseases Research, National Institutes of Health, HHS)

Dated: November 16, 2022.

Tyeshia M. Roberson-Curtis,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2022–25396 Filed 11–21–22; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center for Scientific Review; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: Center for Scientific Review Special Emphasis Panel Small Business: SBIR/STTR Commercialization Readiness Pilot (CRP) Program.

Date: December 5, 2022.

Time: 1:00 p.m. to 4:30 p.m.

Agenda: To review and evaluate grant applications and/or proposals.

Place: National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Allen B Richon, Ph.D., BS, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 6184, MSC 7892, Bethesda, MD 20892, (240) 760-0517, allen.richon@nih.hhs.gov.

This notice is being published less than 15 days prior to the meeting due to the timing limitations imposed by the review and funding cycle.

(Catalogue of Federal Domestic Assistance Program Nos. 93.306, Comparative Medicine; 93.333, Clinical Research, 93.306, 93.333, 93.337, 93.393-93.396, 93.837-93.844, 93.846-93.878, 93.892, 93.893, National Institutes of Health, HHS)

Dated: November 16, 2022.

Tyeshia M. Roberson-Curtis,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2022-25384 Filed 11-21-22; 8:45 am]

BILLING CODE 4140-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center for Scientific Review; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which

would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Small Business: SBIR/STTR Commercialization Readiness Pilot (CRP) Program.

Date: December 5, 2022.

Time: 1:00 p.m. to 4:30 p.m.

Agenda: To review and evaluate grant applications and/or proposals.

Place: National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Allen B Richon, Ph.D., BS, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 6184, MSC 7892, Bethesda, MD 20892, (240) 760-0517, allen.richon@nih.hhs.gov.

This notice is being published less than 15 days prior to the meeting due to the timing limitations imposed by the review and funding cycle.

(Catalogue of Federal Domestic Assistance Program Nos. 93.306, Comparative Medicine; 93.333, Clinical Research, 93.306, 93.333, 93.337, 93.393-93.396, 93.837-93.844, 93.846-93.878, 93.892, 93.893, National Institutes of Health, HHS)

Dated: November 16, 2022.

Tyeshia M. Roberson-Curtis,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2022-25384 Filed 11-21-22; 8:45 am]

BILLING CODE 4140-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Office of The Director; Notice of Charter Renewal

In accordance with Title 41 of the U.S. Code of Federal Regulations, Section 102-3.65(a), notice is hereby given that the Charter for the National Cancer Institute Council of Research Advocates, was renewed for an additional two-year period on August 17, 2022.

It is determined that the National Cancer Institute Council of Research Advocates, is in the public interest in connection with the performance of duties imposed on the National Institutes of Health by law, and that these duties can best be performed through the advice and counsel of this group.

Inquiries may be directed to Claire Harris, Director, Office of Federal Advisory Committee Policy, Office of the Director, National Institutes of Health, 6701 Democracy Boulevard, Suite 1000, Bethesda, Maryland 20892 (Mail code 4875), Telephone (301) 496-2123, or harriscl@mail.nih.gov.

Dated: November 17, 2022.

Melanie J. Pantoja,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2022-25394 Filed 11-21-22; 8:45 am]

BILLING CODE 4140-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Library of Medicine; Cancellation of Meeting

Notice is hereby given of the cancellation of the National Library of Medicine Special Emphasis Panel, March 23, 2023, 11:00 a.m. to 3:00 p.m., Virtual Meeting, which was published in the **Federal Register** on October 6, 2022, 87 FR 193 Page Number 60696.

This notice is being amended to announce that the meeting is cancelled and will not be rescheduled.

Dated: November 16, 2022.

Miguelina Perez,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2022-25340 Filed 11-21-22; 8:45 am]

BILLING CODE 4140-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Environmental Health Sciences; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute of Environmental Health Sciences Special Emphasis Panel: SBIR E-LEARNING for Hazmat and Emergency Response.

Date: December 9, 2022.

Time: 11:00 a.m. to 4:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institute of Environmental Health Science, Keystone Building, 530 Davis Drive Durham, NC 27709 (Virtual Meeting).

Contact Person: Qingdi Quentin Li, MD, Ph.D., Scientific Review Officer, Scientific Review Branch, Division of Extramural Research and Training, Nat'l Institute Environmental Health Sciences, Research Triangle Park, NC 27709, (240) 858-3914, liquenti@nih.gov.

(Catalogue of Federal Domestic Assistance Program Nos. 93.115, Biometry and Risk Estimation—Health Risks from Environmental Exposures; 93.142, NIEHS Hazardous Waste Worker Health and Safety Training; 93.143, NIEHS Superfund Hazardous Substances—Basic Research and Education; 93.894, Resources and Manpower Development in the Environmental Health Sciences; 93.113, Biological Response to Environmental Health Hazards; 93.114, Applied Toxicological Research and Testing, National Institutes of Health, HHS)

Dated: November 16, 2022.

David W. Freeman,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2022-25390 Filed 11-21-22; 8:45 am]

BILLING CODE 4140-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center for Scientific Review; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Neuroimaging and Mechanisms in Development and Psychopathology.

Date: December 15, 2022.

Time: 12:00 p.m. to 4:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Pat Manos, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5200, MSC 7846, Bethesda, MD 20892, (301) 408-9866, manospa@csr.nih.gov.

(Catalogue of Federal Domestic Assistance Program Nos. 93.306, Comparative Medicine;

93.333, Clinical Research, 93.306, 93.333, 93.337, 93.393-93.396, 93.837-93.844, 93.846-93.878, 93.892, 93.893, National Institutes of Health, HHS)

Dated: November 16, 2022.

Tyeshia M. Roberson-Curtis,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2022-25397 Filed 11-21-22; 8:45 am]

BILLING CODE 4140-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Allergy and Infectious Diseases; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute of Allergy and Infectious Diseases Special Emphasis Panel NIAID Clinical Trial Implementation Cooperative Agreement (U01 Clinical Trial Required) and Investigator Initiated Extended Clinical Trial (R01 Clinical Trial Required).

Date: December 16, 2022.

Time: 11:30 a.m. to 2:30 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institute of Allergy and Infectious Diseases, National Institutes of Health, 5601 Fishers Lane, Room 3G42B, Rockville, MD 20892 (Virtual Meeting).

Contact Person: Louis A. Rosenthal, Ph.D., Branch Chief, Scientific Review Program, Division of Extramural Activities, National Institute of Allergy and Infectious Diseases, National Institutes of Health, 5601 Fishers Lane, Room 3G42B, Rockville, MD 20852, (240) 669-5070, rosenthalla@niaid.nih.gov. (Catalogue of Federal Domestic Assistance Program Nos. 93.855, Allergy, Immunology, and Transplantation Research; 93.856, Microbiology and Infectious Diseases Research, National Institutes of Health, HHS)

Dated: November 16, 2022.

Tyeshia M. Roberson-Curtis,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2022-25395 Filed 11-21-22; 8:45 am]

BILLING CODE 4140-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Cancer Institute; Notice of Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of a meeting of the National Cancer Advisory Board and NCI Board of Scientific Advisors.

The meeting will be held as a virtual meeting and is open to the public as indicated below. Individuals who plan to view the virtual meeting and need special assistance or other reasonable accommodations to view the meeting, should notify the Contact Person listed below in advance of the meeting. The meeting will be videocast and can be accessed from the NIH Videocasting and Podcasting website (<http://videocast.nih.gov/>).

A portion of the National Cancer Advisory Board meeting will be closed to the public in accordance with the provisions set forth in section 552b(c)(6), Title 5 U.S.C., as amended. The intramural programs and projects and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the intramural programs and projects, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Cancer Advisory Board and NCI Board of Scientific Advisors.

Date: December 5, 2022.

Closed: 11:00 a.m. to 1:05 p.m.

Agenda: Review of intramural program site visit outcomes and the discussion of confidential personnel issues.

Open: 1:15 p.m. to 4:30 p.m.

Agenda: NCAB Subcommittee Meetings.

Place: National Cancer Institute—Shady Grove, 9609 Medical Center Drive, Rockville, MD 20850 (Virtual Meeting).

Name of Committee: National Cancer Advisory Board and NCI Board of Scientific Advisors.

Date: December 6, 2022.

Open: 1:00 p.m. to 5:30 p.m.

Agenda: Joint meeting of the National Cancer Advisory Board and NCI Board of Scientific Advisors, NCI Director's report and presentations, NCI Board of Scientific Advisors Concepts Review.

Place: National Cancer Institute—Shady Grove, 9609 Medical Center Drive, Rockville, MD 20850 (Virtual Meeting).

Name of Committee: National Cancer Advisory Board and NCI Board of Scientific Advisors.

Date: December 7, 2022.

Open: 1:00 p.m. to 5:00 p.m.

Agenda: Joint meeting of the National Cancer Advisory Board and NCI Board of Scientific Advisors, NCI Board of Scientific Advisors Concepts Review and presentations.

Place: National Cancer Institute—Shady Grove, 9609 Medical Center Drive, Rockville, MD 20850 (Virtual Meeting).

Contact Person: Paulette S. Gray, Ph.D., Director Division of Extramural Activities, National Cancer Institute—Shady Grove, National Institutes of Health, 9609 Medical Center Drive, 7th Floor, Room 7W444, Bethesda, MD 20892, 240–276–6340, grayp@mail.nih.gov.

Any interested person may file written comments with the committee by forwarding the statement to the Contact Person listed on this notice. The statement should include the name, address, telephone number and when applicable, the business or professional affiliation of the interested person.

Information is also available on the Institute's/Center's home page: NCAB: <https://deainfo.nci.nih.gov/advisory/ncab/ncabmeetings.htm>, BSA: <https://deainfo.nci.nih.gov/advisory/bsa/bsameetings.htm>, where an agenda and any additional information for the meeting will be posted when available.

(Catalogue of Federal Domestic Assistance Program Nos. 93.392, Cancer Construction; 93.393, Cancer Cause and Prevention Research; 93.394, Cancer Detection and Diagnosis Research; 93.395, Cancer Treatment Research; 93.396, Cancer Biology Research; 93.397, Cancer Centers Support; 93.398, Cancer Research Manpower; 93.399, Cancer Control, National Institutes of Health, HHS)

Dated: November 17, 2022.

Melanie J. Pantoja,
Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2022–25392 Filed 11–21–22; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Allergy and Infectious Diseases; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute of Allergy and Infectious Diseases Special Emphasis Panel; Asthma and Allergic Diseases Cooperative Research Centers (U19 Clinical Trial Optional).

Date: December 14–15, 2022.

Time: 10:00 a.m. to 6:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institute of Allergy and Infectious Diseases, National Institutes of Health, 5601 Fishers Lane, Room 3G31B, Rockville, MD 20892 (Virtual Meeting).

Contact Person: James T. Snyder, Ph.D., Scientific Review Officer, Scientific Review Program, Division of Extramural Activities, National Institute of Allergy and Infectious Diseases, National Institutes of Health, 5601 Fishers Lane, Room 3G31B, Rockville, MD 20852, (240) 669–5060, james.snyder@nih.gov.

(Catalogue of Federal Domestic Assistance Program Nos. 93.855, Allergy, Immunology, and Transplantation Research; 93.856, Microbiology and Infectious Diseases Research, National Institutes of Health, HHS)

Dated: November 16, 2022.

Tyeshia M. Roberson-Curtis,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2022–25391 Filed 11–21–22; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center for Scientific Review; Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: Center for Scientific Review Special Emphasis Panel; PAR Panel: Fogarty HIV Research Training Program for Low- and Middle-Income Country Institutions.

Date: December 15, 2022.

Time: 9:00 a.m. to 8:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Dayadevi Jirage, Ph.D., Scientific Review Officer, Center for

Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4422, Bethesda, MD 20892, (301) 867–5309, jiragedb@csr.nih.gov.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Member Conflict: Topics in vaccine and drug development for infectious diseases.

Date: December 16, 2022.

Time: 2:00 p.m. to 7:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Jui Pandhare, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, (301) 594–7735, pandharej2@csr.nih.gov.

(Catalogue of Federal Domestic Assistance Program Nos. 93.306, Comparative Medicine; 93.333, Clinical Research, 93.306, 93.333, 93.337, 93.393–93.396, 93.837–93.844, 93.846–93.878, 93.892, 93.893, National Institutes of Health, HHS)

Dated: November 16, 2022.

Tyeshia M. Roberson-Curtis,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2022–25385 Filed 11–21–22; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute on Alcohol Abuse and Alcoholism; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute on Alcohol Abuse and Alcoholism, Initial Review Group; Epidemiology, Prevention and Behavior Research Study Section.

Date: February 28, 2023.

Time: 9:30 a.m. to 5:30 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, National Institute on Alcohol Abuse and

Alcoholism, 6700B Rockledge Drive, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Anna Ghambaryan, M.D., Ph.D., Scientific Review Officer, Extramural Project Review Branch, Office of Extramural Activities, National Institute on Alcohol Abuse and Alcoholism, 6700B Rockledge Drive, Room 2120, MSC 6902, Bethesda, MD 20892, 301-443-4032, anna.ghambaryan@nih.gov.

(Catalogue of Federal Domestic Assistance Program Nos. 93.271, Alcohol Research Career Development Awards for Scientists and Clinicians; 93.272, Alcohol National Research Service Awards for Research Training; 93.273, Alcohol Research Programs; 93.891, Alcohol Research Center Grants; 93.701, ARRA Related Biomedical Research and Research Support Awards., National Institutes of Health, HHS)

Dated: November 17, 2022.

Melanie J. Pantoja,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2022-25393 Filed 11-21-22; 8:45 am]

BILLING CODE 4140-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Substance Abuse and Mental Health Services Administration

Agency Information Collection Activities: Comment Request

AGENCY: Center for Behavioral Health Statistics and Quality; Substance Abuse and Mental Health Services Administration; HHS.

ACTION: Notice.

SUMMARY: Center for Behavioral Health Statistics and Quality (CBHSQ) within the Substance Abuse and Mental Health Services Administration (SAMHSA) invites the general public and other Federal agencies to comment on a proposed information collection. SAMHSA plans to collect information from the public to fulfill its data security requirements when providing access to restricted use microdata for the purpose of evidence building. SAMHSA's data security agreements and other paperwork along with the corresponding security protocols allow SAMHSA to maintain careful controls on confidentiality and privacy, as required by law. The purpose of this notice is to allow for 60 days of public comment on the proposed data security information collection, prior to submission of the information collection request (ICR) to the Office of Management and Budget (OMB).

DATES: Written comments on this notice must be received by January 23, 2023 to be assured of consideration. Comments received after that date will be

considered to the extent practicable. Send comments to the address below.

Comments: Comments are invited on (a) whether the proposed collection of information is necessary for the proper performance of the functions of SAMHSA, including whether the information will have practical utility; (b) the accuracy of SAMHSA's estimate of the burden of the proposed collection of information; (c) ways to enhance the quality, use, and clarity of the information on respondents, including through the use of automated collection techniques or other forms of information technology; and (d) ways to minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology.

FOR FURTHER INFORMATION CONTACT:

Carlos Graham, SAMHSA Reports Clearance Officer, 5600 Fishers Lane, Room 15E57-A, Rockville, Maryland 20857, OR email a copy to Carlos.Graham@samhsa.hhs.gov.

SUPPLEMENTARY INFORMATION: The Foundations for Evidence-Based Policymaking Act of 2018 mandates that the Office of Management and Budget (OMB) establish a Standard Application Process (SAP) for requesting access to certain confidential data assets. While the adoption of the SAP is required for statistical agencies and units designated under the Confidential Information Protection and Statistical Efficiency Act (CIPSEA), it is recognized that other agencies and organizational units within the Executive branch may benefit from the adoption of the SAP to accept applications for access to confidential data assets. The SAP is to be a process through which agencies, the Congressional Budget Office, State, local, and Tribal governments, researchers, and other individuals, as appropriate, may apply to access confidential data assets held by a federal statistical agency or unit for the purposes of developing evidence. With the Interagency Council on Statistical Policy (ICSP) as advisors, the entities upon whom this requirement is levied are working with the SAP Project Management Office (PMO) and with OMB to implement the SAP. The SAP Portal is to be a single web-based common application for the public to request access to confidential data assets from federal statistical agencies and units. The National Center for Science and Engineering Statistics (NCSES), within the National Science Foundation (NSF), submitted a **Federal Register**

Notice in September 2022 announcing plans to collect information through the SAP Portal (87 FR 53793).

Once an application for confidential data is approved through the SAP Portal, SAMHSA will collect information to meet its data security requirements. This collection will occur outside of the SAP Portal.

Title of collection: Data Security Requirements for Accessing Confidential Data.

OMB Control Number: 3145-NEW.

Expiration Date of Current Approval: Not Applicable.

Type of Request: Intent to seek approval to collect information from the public to fulfill [agency name] security requirements allowing individuals to access confidential data assets for the purposes of building evidence.

Abstract: Title III of the Foundations for Evidence-Based Policymaking Act of 2018 (hereafter referred to as the Evidence Act) mandates that OMB establish a Standard Application Process (SAP) for requesting access to certain confidential data assets. Specifically, the Evidence Act requires OMB to establish a common application process through which agencies, the Congressional Budget Office, State, local, and Tribal governments, researchers, and other individuals, as appropriate, may apply for access to confidential data assets collected, accessed, or acquired by a statistical agency or unit. This new process will be implemented while maintaining stringent controls to protect confidentiality and privacy, as required by law.

Data collected, accessed, or acquired by statistical agencies and units is vital for developing evidence on conditions, characteristics, and behaviors of the public and on the operations and outcomes of public programs and policies. This evidence can benefit the stakeholders in the programs, the broader public, as well as policymakers and program managers at the local, State, Tribal, and National levels. The many benefits of access to data for evidence building notwithstanding, SAMHSA is required by law to maintain careful controls that allow it to minimize disclosure risk while protecting confidentiality and privacy. The fulfillment of SAMHSA's data security requirements places a degree of burden on the public, which is outlined below.

The SAP Portal is a web-based application for the public to request access to confidential data assets from federal statistical agencies and units. The objective of the SAP Portal is to increase public access to confidential

data for the purposes of evidence building and reduce the burden of applying for confidential data. Once an individual's application in the SAP Portal has received a positive determination, the data-owning agency(ies) or unit(s) will begin the process of collecting information to fulfill their data security requirements.

The paragraphs below outline the SAP Policy, the steps to complete an application through the SAP Portal, and the process for agencies to collect information fulfilling their data security requirements.

The SAP Policy

At the recommendation of the ICSP, the SAP Policy establishes the SAP to be implemented by statistical agencies and units and incorporates directives from the Evidence Act. The policy is intended to provide guidance as to the application and review processes using the SAP Portal, setting forth clear standards that enable statistical agencies and units to implement a common application form and a uniform review process. The SAP Policy was submitted to the public for comment in January 2022 (87 FR 2459). The policy is currently under review and has not yet been finalized.

The SAP Portal

The SAP Portal is an application interface connecting applicants seeking data with a catalog of data assets owned by the federal statistical agencies and units. The SAP Portal is not a new data repository or warehouse; confidential data assets will continue to be stored in secure data access facilities owned and hosted by the federal statistical agencies and units. The Portal will provide a streamlined application process across agencies, reducing redundancies in the application process. This single SAP Portal will improve the process for applicants, tracking and communicating the application process throughout its lifecycle. This reduces redundancies and burden on applicants that request access to data from multiple agencies. The SAP Portal will automate key tasks to save resources and time and will bring agencies into compliance with the Evidence Act statutory requirements.

Data Discovery

Individuals begin the process of accessing restricted use data by discovering confidential data assets through the SAP data catalog, maintained by federal statistical agencies at www.researchdatagov.org. Potential applicants can search by agency, topic, or keyword to identify data of interest or relevance. Once they

have identified data of interest, applicants can view metadata outlining the title, description or abstract, scope and coverage, and detailed methodology related to a specific data asset to determine its relevance to their research.

While statistical agencies and units shall endeavor to include metadata in the SAP data catalog on all confidential data assets for which they accept applications, it may not be feasible to include metadata for some data assets (e.g., potential curated versions of administrative data). A statistical agency or unit may still accept an application through the SAP Portal even if the requested data asset is not listed in the SAP data catalog.

SAP Application Process

Individuals who have identified and wish to access confidential data assets will be able to apply for access through the SAP Portal when it is released to the public in late 2022. Applicants must create an account and follow all steps to complete the application. Applicants begin by entering their personal, contact, and institutional information, as well as the personal, contact, and institutional information of all individuals on their research team. Applicants proceed to provide summary information about their proposed project, to include project title, duration, funding, timeline, and other details including the data asset(s) they are requesting and any proposed linkages to data not listed in the SAP data catalog, including non-federal data sources. Applicants then proceed to enter detailed information regarding their proposed project, including a project abstract, research question(s), literature review, project scope, research methodology, project products, and anticipated output. Applicants must demonstrate a need for confidential data, outlining why their research question cannot be answered using publicly available information.

Submission for Review

Upon submission of their application, applicants will receive a notification that their application has been received and is under review by the data owning agency or agencies (in the event where data assets are requested from multiple agencies). At this point, applicants will also be notified that application approval does not alone grant access to confidential data, and that, if approved, applicants must comply with the data-owning agency's security requirements outside of the SAP Portal, which may include a background check.

In accordance with the Evidence Act and the direction of the ICSP, agencies will approve or reject an application within a prompt timeframe. In some cases, agencies may determine that additional clarity, information, or modification is needed and request the applicant to "revise and resubmit" their application.

Data discovery, the SAP application process, and the submission for review are planned to take place within the web-based SAP Portal. As noted above, the notice announcing plans to collect information through the SAP Portal has been published separately (87 FR 53793).

Access to Restricted Use Data

In the event of a positive determination, the applicant will be notified that their proposal has been accepted. The positive or final adverse determination concludes the SAP Portal process. In the instance of a positive determination, the data-owning agency (or agencies) will contact the applicant to provide instructions on the agency's security requirements that must be completed to gain access to the confidential data. The completion and submission of the agency's security requirements will take place outside of the SAP Portal.

Collection of Information for Data Security Requirements

In the instance of a positive determination for an application requesting access to an SAMHSA confidential data asset, SAMHSA will contact the applicant(s) to initiate the process of collecting information to fulfill their security requirements. These include additional requirements necessary for the statistical agency or unit to place the applicant(s) in a trusted category that may include the applicant's successful completion of a background investigation, confidentiality training, nondisclosure, and data use agreements.

SAMHSA's data security requirements include the collection of the following information:

- *Researcher's information (personal)*: Name (Last, First, Middle), DOB, citizenship status, home address, home/cell phone number, personal email, Census Special Sworn Status completion.
- *Researcher's employer information*: Employer name, employer address, work phone number, work address, name of supervisor, supervisor's phone number, supervisor's email.
- *Project information*: Title of project, time period researcher expects to be at

the Research Data Center (RDC), signature of researcher, notary signature.

Estimate of Burden: The amount of time to complete the agreements and other paperwork that comprise SAMHSA's security requirements will vary based on the confidential data assets requested and the access modality. To obtain access to SAMHSA's confidential data assets, it is estimated that the average time to complete and submit SAMHSA's data security agreements and other paperwork is 40 minutes. This estimate does not include the time needed to complete and submit an application within the SAP Portal. All efforts related to SAP Portal applications occur prior to and separate from SAMHSA's effort to collect information related to data security requirements.

The expected number of applications in the SAP Portal that receive a positive determination from SAMHSA in a given year may vary. Overall, per year, SAMHSA estimates it will collect data security information for 15 application submissions that received a positive determination within the SAP Portal. SAMHSA estimates that the total burden for the collection of information for data security requirements over the course of the three-year OMB clearance will be about 30 hours and, as a result, an average annual burden of 10 hours.

Carlos Graham,

Reports Clearance Officer.

[FR Doc. 2022-25342 Filed 11-21-22; 8:45 am]

BILLING CODE 4162-20-P

DEPARTMENT OF HOMELAND SECURITY

[Docket No. DHS-2022-0056]

Homeland Security Advisory Council; Meeting

AGENCY: The Department of Homeland Security (DHS), The Office of Partnership and Engagement (OPE).

ACTION: Notice of open Federal Advisory Committee meeting.

SUMMARY: The Homeland Security Advisory Council (HSAC) will hold a public meeting on Tuesday, December 6, 2022. The meeting will be open to the public via web conference.

DATES: The meeting will take place from 2 p.m. ET to 4 p.m. ET on Tuesday, December 6, 2022. Please note that the meeting may end early if the Council has completed its business.

ADDRESSES: The HSAC meeting will be held at the Federal Emergency Management Agency (FEMA)

headquarters in Washington, DC. Members of the public interested in participating may do so by following the process outlined below. The public will be in listen-only mode except for the public comment portion of the meeting. Written comments can be submitted from November 28, 2022 to December 6, 2022. Comments must be identified by Docket No. DHS-2022-0056 and may be submitted by one of the following methods:

- **Federal eRulemaking Portal:** <http://www.regulations.gov>. Follow the instructions for submitting comments.

- **Email:** HSAC@hq.dhs.gov. Include Docket No. DHS-2022-0056 in the subject line of the message.

- **Mail:** Rebecca Sternhell, Executive Director of the Homeland Security Advisory Council, Office of Partnership and Engagement, Mailstop 0385, Department of Homeland Security, 2707 Martin Luther King Jr Ave. SE, Washington, DC 20528.

Instructions: All submissions received must include the words "Department of Homeland Security" and "DHS-2022-0056," the docket number for this action. Comments received will be posted without alteration at <http://www.regulations.gov>, including any personal information provided. You may wish to review the Privacy and Security Notice found via a link on the homepage of www.regulations.gov.

Docket: For access to the docket to read comments received by the Council, go to <http://www.regulations.gov>, search "DHS-2022-0056," "Open Docket Folder" to view the comments.

FOR FURTHER INFORMATION CONTACT:

Rebecca Sternhell at 202-891-2876 or HSAC@hq.dhs.gov.

SUPPLEMENTARY INFORMATION: Notice of this meeting is given under Section 10(a) of the Federal Advisory Committee Act (FACA), Public Law 92-463 (5 U.S.C. Appendix), which requires each FACA committee meeting to be open to the public unless the President, or the head of the agency to which the advisory committee reports, determines that a portion of the meeting may be closed to the public in accordance with 5 U.S.C. 552b(c).

The HSAC provides organizationally independent, strategic, timely, specific, actionable advice, and recommendations to the Secretary of Homeland Security on matters related to homeland security. The Council consists of senior executives from government, the private sector, academia, law enforcement, and non-governmental organizations. The meeting will include:

(1) Remarks from Senior DHS leaders,

(2) Introduction and swearing in of new members,

(3) Updates from new subcommittees, and

(4) Receipt of and vote on the draft report from the Customer Experience and Service Delivery Subcommittee.

Members of the public will be in listen-only mode except during the public comment session. Members of the public may register to participate in this Council meeting via web conference under the following procedures. Each individual must provide their full legal name and email address no later than 5 p.m. ET on Friday, December 2, 2022 to Rebecca Sternhell of the Council via email to HSAC@hq.dhs.gov or via phone at 202-891-2876. Members of the public who have registered to participate will be provided the weblink after the closing of the public registration period and prior to the start of the meeting.

For information on services for individuals with disabilities, or to request special assistance, please email HSAC@hq.dhs.gov by 5 p.m. ET on December 2, 2022 or call 202-891-2876. The HSAC is committed to ensuring all participants have equal access regardless of disability status. If you require a reasonable accommodation due to a disability to fully participate, please contact Rebecca Sternhell at 202-891-2876 or HSAC@hq.dhs.gov as soon as possible.

Dated: November 16, 2022.

Rebecca K. Sternhell,

Executive Director, Homeland Security Advisory Council, Department of Homeland Security.

[FR Doc. 2022-25361 Filed 11-21-22; 8:45 am]

BILLING CODE 9112-FN-P

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

[Docket No. FR-7056-N-52; OMB Control No. 2502-0305]

60-Day Notice of Proposed Information Collection: Management Certification & Entity Profile

AGENCY: Office of the Assistant Secretary for Housing—Federal Housing Commissioner, HUD.

ACTION: Notice.

SUMMARY: HUD is seeking approval from the Office of Management and Budget (OMB) for the information collection described below. In accordance with the Paperwork Reduction Act, HUD is requesting comment from all interested parties on the proposed collection of information. The purpose of this notice is to allow for 60 days of public comment.

DATES: *Comments Due Date:* January 23, 2023.

ADDRESSES: Interested persons are invited to submit comments regarding this proposal. Comments should refer to the proposal by name and/or OMB Control Number and should be sent to: Colette Pollard, Reports Management Officer, REE, Department of Housing and Urban Development, 451 7th Street SW, Room 4176, Washington, DC 20410–5000; telephone 202–402–3400 (this is not a toll-free number) or email at Colette.Pollard@hud.gov for a copy of the proposed forms or other available information. HUD welcomes and is prepared to receive calls from individuals who are deaf or hard of hearing, as well as individuals with speech and communication disabilities. To learn more about how to make an accessible telephone call, please visit <https://www.fcc.gov/consumers/guides/telecommunications-relay-service-trs>.

FOR FURTHER INFORMATION CONTACT: Colette Pollard, Reports Management Officer, REE, Department of Housing and Urban Development, 451 7th Street SW, Washington, DC 20410; email Colette.Pollard@hud.gov or telephone 202–402–3400. This is not a toll-free number. HUD welcomes and is prepared to receive calls from individuals who are deaf or hard of hearing, as well as individuals with speech and communication disabilities. To learn more about how to make an accessible telephone call, please visit <https://www.fcc.gov/consumers/guides/telecommunications-relay-service-trs>.

Copies of available documents submitted to OMB may be obtained from Ms. Pollard.

SUPPLEMENTARY INFORMATION: This notice informs the public that HUD is seeking approval from OMB for the information collection described in Section A.

A. Overview of Information Collection

Title of Information Collection: Management Certification & Entity Profile.

OMB Approval Number: 2502–0305.

OMB Expiration Date: 09/30/2023.

Type of Request: Reinstatement, without change, of previously approved collection for which approval has expired.

Form Number: HUD–9832 Management Entity Profile; HUD–9839–a Project Owner’s Certification for Owner-Managed Multifamily Housing Projects; HUD–9839–b Project Owner’s/Management Agent’s Certification for Multifamily Housing Projects for Identity-of-Interest or Independent

Management Agents; HUD–9839–c Project Owner’s/Borrower’s Certification for Elderly Housing Projects Managed by Administrators.

Description of the need for the information and proposed use: Owners of HUD-held, -insured, or subsidized multifamily housing projects must provide information for HUD’s oversight of management agents/entities.

Respondents: Property owners; project managers.

Estimated Number of Respondents: 61,240.

Estimated Number of Responses: 3,062.

Frequency of Response: 1.

Average Hours per Response: Varies.

Total Estimated Burden: 3,540.

B. Solicitation of Public Comment

This notice is soliciting comments from members of the public and affected parties concerning the collection of information described in Section A on the following:

(1) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;

(2) The accuracy of the agency’s estimate of the burden of the proposed collection of information;

(3) Ways to enhance the quality, utility, and clarity of the information to be collected; and

(4) Ways to minimize the burden of the collection of information on those who are to respond; including through the use of appropriate automated collection techniques or other forms of information technology, e.g., permitting electronic submission of responses.

HUD encourages interested parties to submit comment in response to these questions.

C. Authority

Section 3507 of the Paperwork Reduction Act of 1995, 44 U.S.C. Chapter 35.

Jeffrey D. Little,

General Deputy Assistant Secretary, Office of Housing.

[FR Doc. 2022–25349 Filed 11–21–22; 8:45 am]

BILLING CODE 4210–67–P

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

[Docket No. FR–7056–N–46; OMB Control No. 2502–0614]

60-Day Notice of Proposed Information Collection: HUD Certified Housing Counselor Registration

AGENCY: Office of the Assistant Secretary for Housing—Federal Housing Commissioner, HUD.

ACTION: Notice.

SUMMARY: HUD is seeking approval from the Office of Management and Budget (OMB) for the information collection described below. In accordance with the Paperwork Reduction Act, HUD is requesting comment from all interested parties on the proposed collection of information. The purpose of this notice is to allow for 60 days of public comment.

DATES: *Comments Due Date:* January 23, 2023.

ADDRESSES: Interested persons are invited to submit comments regarding this proposal. Comments should refer to the proposal by name and/or OMB Control Number and should be sent to: Colette Pollard, Reports Management Officer, Department of Housing and Urban Development, 451 7th Street SW, Washington, DC 20410; telephone 202–402–3400 (this is not a toll-free number) or email at Colette.Pollard@hud.gov for a copy of the proposed forms or other available information. HUD welcomes and is prepared to receive calls from individuals who are deaf or hard of hearing, as well as individuals with speech and communication disabilities. To learn more about how to make an accessible telephone call, please visit <https://www.fcc.gov/consumers/guides/telecommunications-relay-service-trs>.

FOR FURTHER INFORMATION CONTACT: Colette Pollard, Reports Management Officer, Department of Housing and Urban Development, 451 7th Street SW, Washington, DC 20410; email Colette.Pollard@hud.gov or telephone 202–402–3400. This is not a toll-free number. HUD welcomes and is prepared to receive calls from individuals who are deaf or hard of hearing, as well as individuals with speech and communication disabilities. To learn more about how to make an accessible telephone call, please visit <https://www.fcc.gov/consumers/guides/telecommunications-relay-service-trs>.

Copies of available documents submitted to OMB may be obtained from Ms. Pollard.

SUPPLEMENTARY INFORMATION: This notice informs the public that HUD is

seeking approval from OMB for the information collection described in Section A.

A. Overview of Information Collection

Title of Information Collection: HUD Certified Housing Counselor Registration.

OMB Approval Number: 2502–0614.

OMB Expiration Date: 8–31–2023.

Type of Request: Revision of a currently approved collection.

Form Number: None.

Description of the need for the information and proposed use: The information will be collected on the Office of Housing Counseling, HUD Housing Counselor Certification Training and Examination website, www.HUDHousingCounselors.com, and with the housing counselor's completion and electronic submission of their information through the website, it will be transferred to the HUD Federal Housing Administration Connection system. The information collected will be used to certify housing counselors.

Respondents: Individuals or households.

Estimated Number of Respondents: 3,900.

Estimated Number of Responses: 3,900.

Frequency of Response: Once.

Average Hours per Response: 0.25 hours.

Total Estimated Burden: 975 hours.

B. Solicitation of Public Comment

This notice is soliciting comments from members of the public and affected parties concerning the collection of information described in Section A on the following:

(1) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;

(2) The accuracy of the agency's estimate of the burden of the proposed collection of information;

(3) Ways to enhance the quality, utility, and clarity of the information to be collected; and

(4) Ways to minimize the burden of the collection of information on those who are to respond; including through the use of appropriate automated collection techniques or other forms of information technology, e.g., permitting electronic submission of responses.

HUD encourages interested parties to submit comment in response to these questions.

C. Authority

Section 3507 of the Paperwork Reduction Act of 1995, 44 U.S.C. 3507.

Jeffrey D. Little,

General Deputy Assistant Secretary for Housing.

[FR Doc. 2022–25347 Filed 11–21–22; 8:45 am]

BILLING CODE 4210–67–P

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

[Docket No. FR–7056–N–49; OMB Control No: 2502–0010]

60-Day Notice of Proposed Information Collection: Land Survey Report for Insured Multifamily Projects; (Form HUD–92457)

AGENCY: Office of the Assistant Secretary for Housing—Federal Housing Commissioner, HUD.

ACTION: Notice.

SUMMARY: HUD is seeking approval from the Office of Management and Budget (OMB) for the information collection described below. In accordance with the Paperwork Reduction Act, HUD is requesting comment from all interested parties on the proposed collection of information. The purpose of this notice is to allow for 60 days of public comment.

DATES: *Comments Due Date:* January 23, 2023.

ADDRESSES: Interested persons are invited to submit comments regarding this proposal. Comments should refer to the proposal by name and/or OMB Control Number and should be sent to: Colette Pollard, Reports Management Officer, REE, Department of Housing and Urban Development, 451 7th Street SW, Room 4176, Washington, DC 20410–5000; telephone 202–402–3400 (this is not a toll-free number) or email at Colette.Pollard@hud.gov for a copy of the proposed forms or other available information. HUD welcomes and is prepared to receive calls from individuals who are deaf or hard of hearing, as well as individuals with speech and communication disabilities. To learn more about how to make an accessible telephone call, please visit <https://www.fcc.gov/consumers/guides/telecommunications-relay-service-trs>.

FOR FURTHER INFORMATION CONTACT: Colette Pollard, Reports Management Officer, REE, Department of Housing and Urban Development, 451 7th Street SW, Washington, DC 20410; email Colette Pollard at Colette.Pollard@hud.gov or telephone 202–402–3400. This is not a toll-free number. HUD

welcomes and is prepared to receive calls from individuals who are deaf or hard of hearing, as well as individuals with speech and communication disabilities. To learn more about how to make an accessible telephone call, please visit <https://www.fcc.gov/consumers/guides/telecommunications-relay-service-trs>.

Copies of available documents submitted to OMB may be obtained from Ms. Pollard.

SUPPLEMENTARY INFORMATION: This notice informs the public that HUD is seeking approval from OMB for the information collection described in Section A.

A. Overview of Information Collection

Title of Information Collection: Land Survey Report for Insured Multifamily Projects.

OMB Approval Number: 2502–0010.

Type of Request: Reinstatement, with change, of previously approved collection for which approval has expired on 7/31/2021.

Form Number: HUD–92457.

Description of the need for the information and proposed use: The information collection is being reinstated to be discontinued. The Form HUD–92457, HUD's Survey Instructions and Report for Insured Multifamily has been deleted from this collection due to duplication and is a loan closing document found under OMB–2502–0598.

Respondents: Profit motivated, non-profit.

Estimated Number of Respondents: 200.

Estimated Number of Responses: 400.

Frequency of Response: 2.

Average Hours per Response: 0.50.

Total Estimated Burden: 200.

B. Solicitation of Public Comment

This notice is soliciting comments from members of the public and affected parties concerning the collection of information described in Section A on the following:

(1) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;

(2) The accuracy of the agency's estimate of the burden of the proposed collection of information;

(3) Ways to enhance the quality, utility, and clarity of the information to be collected; and

(4) Ways to minimize the burden of the collection of information on those who are to respond; including through the use of appropriate automated collection techniques or other forms of

information technology, *e.g.*, permitting electronic submission of responses.

HUD encourages interested parties to submit comment in response to these questions.

C. Authority

Section 3507 of the Paperwork Reduction Act of 1995, 44 U.S.C. Chapter 35.

Jeffrey D. Little,

General Deputy Assistant Secretary, Office of Housing.

[FR Doc. 2022-25348 Filed 11-21-22; 8:45 am]

BILLING CODE 4210-67-P

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

[Docket No. FR-7052-N-06; OMB Control No. 2506-0165]

60-Day Notice of Proposed Information Collection: Disaster Recovery Grant Reporting System

AGENCY: Office of Community Planning and Development, HUD.

ACTION: Notice.

SUMMARY: HUD is seeking approval from the Office of Management and Budget (OMB) for the information collection described below. In accordance with the Paperwork Reduction Act, HUD is requesting comment from all interested parties on the proposed collection of information. The purpose of this notice is to allow for 60 days of public comment.

DATES: *Comments Due Date:* January 23, 2023.

ADDRESSES: Interested persons are invited to submit comments regarding this proposal. Comments should refer to the proposal by name and/or OMB Control Number and should be sent to: Anna Guido, Management Analyst, REE, Department of Housing and Urban Development, 451 7th Street SW, Room 4176, Washington, DC 20410-5000; telephone 202-402-5535 (this is not a toll-free number) or email at Anna.P.Guido@HUD.Gov for a copy of the proposed forms or other available information. HUD welcomes and is prepared to receive calls from individuals who are deaf or hard of hearing, as well as individuals with speech and communication disabilities. To learn more about how to make an accessible telephone call, please visit <https://www.fcc.gov/consumers/guides/telecommunications-relay-service-trs>.

FOR FURTHER INFORMATION CONTACT: Tennille Smith Parker, Director, Disaster Recovery and Special Issues Division, Office of Block Grant Assistance,

Department of Housing and Urban Development, 451 7th Street SW, Washington, DC 20410; email Tennille.Parker@HUD.gov or telephone 202-708-3587. This is not a toll-free number. HUD welcomes and is prepared to receive calls from individuals who are deaf or hard of hearing, as well as individuals with speech and communication disabilities. To learn more about how to make an accessible telephone call, please visit <https://www.fcc.gov/consumers/guides/telecommunications-relay-service-trs>. Copies of available documents submitted to OMB may be obtained from Ms. Guido.

SUPPLEMENTARY INFORMATION: This notice informs the public that HUD is seeking approval from OMB for the information collection described in Section A.

A. Overview of Information Collection

Title of Information Collection: Disaster Recovery Grant Reporting System (DRGR).

OMB Approval Number: 2506-0165.

Type of Request: Revision.

Form Number: SF-424 Application for Federal Assistance.

Description of the need for the information and proposed use:

The Disaster Recovery Grant Reporting (DRGR) System is a grants management system used by the Office of Community Planning and Development to monitor special appropriation grants under the Community Development Block Grant program. This collection pertains to Community Development Block Grant Disaster Recovery (CDBG-DR), Community Development Block Grant Mitigation (CDBG-MIT), Community Development Block Grant National Disaster Resilience Competition (CDBG-NDR), Neighborhood Stabilization Program (NSP), Rural Capacity Building (RCB), Section 4, and Recovery Housing Program (RHP) grant funds.

The CDBG program is authorized under Title I of the Housing and Community Development Act of 1974, as amended. Following major disasters, Congress appropriates supplemental CDBG funds for disaster recovery. According to Section 104(e)(1) of the Housing and Community Development Act of 1974, HUD is responsible for reviewing grantees' compliance with applicable requirements and their continuing capacity to carry out their programs. Grant funds are made available to states and units of general local government, Indian tribes, and insular areas, unless provided otherwise by supplemental appropriations statute,

based on their unmet disaster recovery needs.

The Neighborhood Stabilization Program (NSP) was established for the purpose of stabilizing communities that have suffered from foreclosures and property abandonment. Authorized under Section 1497 of the Wall Street Reform and Consumer Protection Act of 2010 (Pub. L. 111-203, approved July 21, 2010) ("NSP3"), NSP3 Technical Assistance (TA) provides \$20 million to organizations that are experienced and successful in providing program, technical, planning, financial, and organizational capacity building assistance, or consulting in such areas as community development, affordable housing, organizational management, financing and underwriting, construction and rehabilitation management, land banking, project management and strategic planning.

Through the funding of national organizations with expertise in rural housing and community development, the Rural Capacity Building (RCB) and Section 4 programs enhance the capacity and ability of local governments, Indian tribes, housing development organizations, rural Community Development Corporations (CDCs), and rural Community Housing Development Organizations (CHDOs), to carry out community development and affordable housing activities that benefit low-and moderate-income families and persons in rural areas.

The Recovery Housing Program (RHP) was authorized under section 8071 of the Support for Patients and Communities (SUPPORT) Act. HUD published its formula in the **Federal Register** on April 17, 2019 (84 FR 16027), identifying the 35 eligible grantees and allocation percentages. Section 8071 of the SUPPORT Act (Section 8071) required funds appropriated or made available for the RHP be treated as CDBG funds under title I of the Housing and Community Act of 1974, unless otherwise provided in Section 8071 or modified by waivers and alternative requirements.

Estimated Number of Respondents: 2,378.

Estimated Number of Responses: 46,150.

Frequency of Response: Varies.

Average Hours per Response: Varies.

Total Estimated Burdens: 59,890.50 hours and cost of \$1,861,995.10.

B. Solicitation of Public Comment

This notice is soliciting comments from members of the public and affected parties concerning the collection of information described in Section A on the following:

(1) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;

(2) The accuracy of the agency's estimate of the burden of the proposed collection of information;

(3) Ways to enhance the quality, utility, and clarity of the information to be collected; and

(4) Ways to minimize the burden of the collection of information on those who are to respond; including through the use of appropriate automated collection techniques or other forms of information technology, *e.g.*, permitting electronic submission of responses.

HUD encourages interested parties to submit comment in response to these questions.

C. Authority

Section 3507 of the Paperwork Reduction Act of 1995, 44 U.S.C. Chapter 35.

Principal Deputy Assistant Secretary for Community Planning and Development, Marion McFadden, having reviewed and approved this document, is delegating the authority to electronically sign this document to submitter, Aaron Santa Anna, who is the Federal Register Liaison for HUD, for purposes of publication in the **Federal Register**.

Aaron Santa Anna,

Federal Liaison for the Department of Housing and Urban Development.

[FR Doc. 2022-25365 Filed 11-21-22; 8:45 am]

BILLING CODE 4210-67-P

DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

[Docket No. FWS-HQ-ES-2022-0107; FF09E42000-FXES111609BFEDR-223]

John H. Chafee Coastal Barrier Resources System; Michigan, Minnesota, Mississippi, North Carolina, Ohio, South Carolina, Texas, and Wisconsin; Draft 5-Year Review Boundaries

AGENCY: Fish and Wildlife Service, Interior.

ACTION: Notice of availability; request for comments.

SUMMARY: The Coastal Barrier Resources Act requires the Secretary of the Interior to review the maps of the John H. Chafee Coastal Barrier Resources System (CBRS) at least once every 5 years and make any minor and technical modifications to the boundaries of the CBRS as are necessary to reflect changes that have occurred in the size or

location of any unit as a result of natural forces. We, the U.S. Fish and Wildlife Service, have conducted this review for CBRS units in Michigan, Minnesota, Mississippi, North Carolina, Ohio, South Carolina, Texas, and Wisconsin. This notice announces the findings of our review and request for comments on the draft revised boundaries from Federal, State, and local officials.

DATES: To ensure consideration, we must receive your written comments by December 22, 2022.

ADDRESSES: You may submit written comments by one of the following methods:

- *Electronically:* Go to the: <https://www.regulations.gov>. Search for FWS-HQ-ES-2022-0107, which is the docket number for this notice.

- *By hard copy:* Submit by U.S. mail or hand-delivery to: Public Comments Processing, Attn: Docket No. FWS-HQ-ES-2022-0107, U.S. Fish and Wildlife Service, 5275 Leesburg Pike, MS: PRB/3W, Falls Church, VA 22041-3808.

We request that you send comments by only one of the methods described above. We will post all information received on <https://www.regulations.gov>. If you provide personal identifying information in your comment, you may request at the top of your document that we withhold this information from public review. However, we cannot guarantee that we will be able to do so.

FOR FURTHER INFORMATION CONTACT:

Katie Niemi, Coastal Barriers Coordinator, via telephone at 703-358-2071, by email at CBRA@fws.gov. Individuals in the United States who are deaf, deafblind, hard of hearing, or have a speech disability may dial 711 (TTY, TDD, or TeleBraille) to access telecommunications relay services. Individuals outside the United States should use the relay services offered within their country to make international calls to the point-of-contact in the United States.

SUPPLEMENTARY INFORMATION: The Coastal Barrier Resources Act (CBRA; 16 U.S.C. 3501 *et seq.*) requires the Secretary of the Interior (Secretary) to review the maps of the John H. Chafee Coastal Barrier Resources System (CBRS) at least once every 5 years and make, in consultation with the appropriate Federal, State, and local officials, such minor and technical modifications to the boundaries of the CBRS as are necessary solely to reflect changes that have occurred in the size or location of any unit as a result of natural forces (16 U.S.C. 3503(c)).

The U.S. Fish and Wildlife Service's (Service) review included:

- All 46 units located in Michigan.
- One (the only) unit located in Minnesota.
- All 7 units located in Mississippi.
- All 17 units located in North Carolina.
- All 10 units located in Ohio.
- Ten of the 23 total units in South Carolina.
- All 35 units located in Texas.
- All 7 units located in Wisconsin

Of the 133 total units reviewed, the Service revised 18 units that had experienced changes in their sizes or locations as a result of natural forces since they were last mapped. The North Carolina units will be reviewed again in 2023 due to ongoing geomorphic change in certain units and the need for additional data.

Background on the Coastal Barrier Resources System

Coastal barrier ecosystems are located at the interface of land and sea and are subject to continual geomorphic change (*e.g.*, erosion and accretion). Coastal barriers and their associated aquatic habitat (wetlands and open water) provide important habitat for fish and wildlife and serve as the mainland's first line of defense against the impacts of severe storms. With the passage of CBRA in 1982, Congress recognized that certain actions and programs of the Federal Government have historically subsidized and encouraged development on storm-prone and highly dynamic coastal barriers, and the result has been the loss of natural resources; threats to human life, health, and property; and the expenditure of billions of tax dollars.

CBRA established the CBRS, which originally comprised 186 geographic units encompassing approximately 453,000 acres of relatively undeveloped lands and associated aquatic habitat along the Atlantic and Gulf of Mexico coasts. The CBRS was expanded by the Coastal Barrier Improvement Act of 1990 (Pub. L. 101-591) to include additional areas along the Atlantic and Gulf of Mexico coasts, as well as areas along the coasts of the Great Lakes, the U.S. Virgin Islands, and Puerto Rico.

The CBRS now comprises a total of 870 geographic units, encompassing approximately 3.5 million acres of land and associated aquatic habitat. These areas are depicted on a series of official maps. Most new Federal expenditures and financial assistance are prohibited within the CBRS. Development can still occur within the CBRS, provided that it is not subsidized by the Federal Government.

The CBRS includes two types of units, System Units and Otherwise Protected Areas (OPAs). System Units contain

areas that were relatively undeveloped and predominantly privately owned at the time of designation, though they may also contain areas held for conservation and/or recreation. Most new Federal expenditures and financial assistance, including Federal flood insurance, are prohibited within System Units. OPAs are predominantly comprised of conservation and/or recreation areas such as national wildlife refuges, State and national parks, and local and private conservation areas, though they may also contain private areas not held for conservation and/or recreation. OPAs are denoted with a “P” at the end of the unit number. The only Federal spending prohibition within OPAs is on flood insurance.

5-Year Review Authority

The Secretary, through the Service, is responsible for administering CBRA, which includes maintaining and updating the official maps of the CBRS, consulting with Federal agencies that propose to spend funds within the CBRS, and making recommendations to Congress regarding proposed changes to the CBRS. With three narrow exceptions, only Congress—through new legislation—can modify the maps of the CBRS to add or remove areas.

The three exceptions authorize the Secretary to:

1. Review the maps of the CBRS at least once every 5 years and make any minor and technical modifications to the boundaries of the CBRS as are necessary to reflect changes that have occurred in the size or location of any CBRS unit as a result of natural forces (16 U.S.C. 3503(c); this process is known as the “5-year review”);
2. Add a parcel of real property to the CBRS if:
 - a. the owner of the parcel requests, in writing, that the Secretary add the parcel to the CBRS; and
 - b. the parcel is an undeveloped coastal barrier (16 U.S.C. 3503(d)); and
3. Add excess Federal property to the CBRS following consultation with the Administrator of the U.S. General Services Administration and a determination that the property (or a portion of it) constitutes an undeveloped coastal barrier (16 U.S.C. 3503(e)).

Changes that are outside the scope of these three authorities cannot be made by the Service administratively. Rather, such changes must be made through the comprehensive map modernization process, which is more time consuming and resource-intensive because it entails significant research, public review, and congressional enactment of the revised

maps. Comprehensive map modernization not only transfers the CBRS boundaries to a new base map and makes any modifications necessary to account for natural changes, but also corrects errors that affect property owners and adds areas appropriate for inclusion to the CBRS (beyond those additions authorized under 16 U.S.C. 3503(c)–(e)). Additional information about this process can be found in a notice the Service published in the **Federal Register** on January 4, 2021 (86 FR 118) and at: <https://www.fws.gov/program/coastal-barrier-resources-act/what-we-do>.

5-Year Review Schedule

The Service last completed the 5-year review for 19 of the 23 States and territories that currently contain CBRS units between 2014 and 2016. Additional information about that 5-year review is available at <https://www.fws.gov/project/digital-conversion-and-5-year-review>. The remainder of the CBRS units that did not go through that 5-year review process (located in Connecticut, Massachusetts, Rhode Island, and the Long Island region of New York) were comprehensively revised through the Hurricane Sandy Remapping Project, which incorporated changes due to natural forces in addition to other more significant changes that have been recommended to Congress. The maps produced through the Hurricane Sandy Remapping Project were transmitted to Congress for consideration in April 2022 and must be adopted through legislation to become effective.

With this notice, the Service initiates a new 5-year review cycle, which is planned to include approximately 450 units in three batches between 2022 and 2025. The units included in each batch are prioritized by considering the following factors: (1) the age of the current effective maps, with the oldest maps generally being revised first; (2) the availability of recent high-resolution aerial imagery (based on the anticipated U.S. Department of Agriculture National Agriculture Imagery Program [NAIP] acquisition schedule); and (3) avoiding overlaps between 5-year review and comprehensive map modernization projects, which can cause confusion and result in duplicated effort. The schedule and batching for the 5-year review are subject to change, based upon the availability of aerial imagery that meets the standards described in the 5-Year Review Methodology section below and changes to our comprehensive remapping schedule. Information regarding the 5-year review is available

on the Service’s website at: <https://www.fws.gov/project/cbrs-5-year-review>.

5-Year Review Methodology

The methodology described below is the general process through which the Service conducts a review of the CBRS units to identify areas where natural change has occurred and to produce revised maps through the 5-year review. Through the 5-year review effort, the existing CBRS boundaries are reviewed against updated base maps (*i.e.*, a recent aerial image) to identify any natural changes that have occurred since the maps were last updated.

Base Map Selection and Base Fitting

Base map selection and base fitting are the first steps in the 5-year review process. A base map is a map depicting background reference information—such as landforms, roads, landmarks, and political boundaries—onto which other thematic information is overlaid. The Service selects aerial imagery to serve as the CBRS base map that is recent (generally less than 3 years old), high resolution (1 meter per pixel resolution or better), orthorectified (*i.e.*, adjusted to ensure the proper perspective of features relative to their true position on the Earth’s surface), and available free of charge. The base map for this 5-year review will primarily be NAIP imagery.

CBRS boundaries are generally intended to follow natural and development features on the ground, such as shorelines, stream channels, edges of marshes or wetlands, roads, structures, and jetties. These features may appear in slightly different locations when viewed on different base maps due to minor differences in their georeferencing (*i.e.*, alignment to a known geographic coordinate system) and/or orthorectification. The CBRS boundaries must be fit to these same features on the new base map in cases where small but significant differences are noted. If the intent of a particular boundary segment was clearly to follow an identifiable natural or development feature, the digital boundary is adjusted to the appropriate feature on the new base map. However, the extent of such adjustments is limited to the width of the existing boundary line depicted on the official map (which translates to about 20 feet on the Earth’s surface). These adjustments are also within the stated horizontal accuracy range of NAIP imagery, which is also about 20 feet.

Base-fitting adjustments are not made through the 5-year review if the intent of a particular boundary segment cannot be determined; the underlying feature

has clearly undergone human-generated change; or the boundary line on the official map is more than 20 feet from the actual feature it was intended to follow on the ground (unless geomorphic change has occurred, as described in the section below). Some changes are beyond the scope of the 5-year review and may require further review through the comprehensive map modernization effort that is described earlier in this notice.

Boundary Modifications To Account for Natural Changes

The Service assesses the current official CBRS maps, as well as historical and current aerial imagery, to determine where natural changes (e.g., eroded shorelines, accreted sand spits) have occurred since the maps were last updated. Where the intent of a boundary segment was clearly to follow a geomorphic feature on the ground, and that feature had undergone natural change, the boundary on the map is modified to follow the present location of the geomorphic feature and/or the aquatic habitat associated with the feature. Associated aquatic habitat may include the adjacent wetlands, marshes, estuaries, inlets, and nearshore waters associated with the fastland component of the coastal barrier. The term “fastland” refers to the portion of a coastal barrier between the mean high tide line on the ocean side, and the upper limit of tidal vegetation (or, if such vegetation is not present, the mean high tide line) on the landward side of the coastal barrier.

In some cases, portions of the landward boundary are modified to reflect natural changes to the wetland/fastland interface. The “wetland/fastland interface” is a transitional area between wetlands and fastland, or land that is predominantly wet and land that is predominantly dry. This interface is identified for CBRS mapping purposes through aerial photo interpretation, supported in some cases by National Wetlands Inventory data (<https://www.fws.gov/program/national-wetlands-inventory>).

In cases where no such boundary changes are necessary, the Service will generally reissue the maps with updated base map imagery. Updating the imagery (even when there are no boundary changes) is useful because geomorphic changes are likely to have occurred within the interior of many units, even if they do not affect the outer boundaries of the units. Updated imagery also improves the usability of the maps to reflect changes in road networks and other features that serve as reference points to map users. In

limited cases, to avoid confusion, the Service may choose not to reissue a map if there are no geomorphic changes and there is another draft revised map for the area undergoing review by Congress.

Map Paneling

Each official CBRS map covers a spatial extent roughly equivalent to one U.S. Geological Survey 7.5-minute topographic quadrangle; this spatial extent is referred to as a “map panel.” There are some places where the existing CBRS map panels overlap each other, and yet provide no indication that there is another CBRS unit in the same area that is shown on a different map panel. This omission is a source of confusion for users who assume that, if no CBRS unit is depicted on a specific CBRS map, then there is no CBRS unit in that area.

Rather than making static draft maps for stakeholder review, the Service will use a web mapping application to display proposed 5-year review changes to the CBRS boundaries. Following the close of the stakeholder review period, the Service will address the issue of map panel overlaps where possible by repaneling the affected areas. The existing map panels will be shifted and/or combined to eliminate overlaps, and all CBRS units on a given map panel will be depicted. Changes to the configuration of the CBRS map panels do not affect the placement of the CBRS boundaries but will help reduce confusion and improve the usability of the official CBRS maps.

Proposed Modifications to the CBRS

In accordance with CBRA’s requirement to update the CBRS maps at least once every 5 years to account for natural changes, the Service has conducted a review of certain unit boundaries in Michigan, Minnesota, Mississippi, Ohio, North Carolina, South Carolina, Texas, and Wisconsin. (See the list at the beginning of this section.) The remaining 13 South Carolina units are not included in this review either because they were either comprehensively reviewed recently or they will be included in a more comprehensive review (beyond the scope of the 5-year review) at a later date, at which time the Service will also complete an assessment of changes necessary due to natural forces.

The Service made modifications due to natural changes in the size or location of a total of 18 CBRS units (of the 133 units reviewed). Below is a summary of those changes and the results of our review.

Michigan

The Service’s review found that 3 of the 46 CBRS units in Michigan require changes due to natural forces. The imagery that was used on the current effective maps is dated 2012. The imagery that was used for this review, and will be used for the revised maps, is dated 2020. Additionally, one adjustment was needed to the northern lateral boundary of Sadony Bayou Unit MI-22 to maintain the relationship between the boundary and a structure that was on the ground prior to the designation of the CBRS unit in 1990. This structure appeared to be outside of the unit on the 2012 NAIP imagery used for the currently effective map but appears to be within the unit on the 2020 imagery due to an approximately 10-foot difference in location between the two images. The boundary has been adjusted to the south by about 10 feet to maintain the relationship between the boundary and the structure that is depicted on the currently effective CBRS map.

In September 2022, the Board on Geographic Names voted to replace the names of nearly 650 geographic features that had previously featured a derogatory word for indigenous women. These name changes affect three Michigan units, which have been updated accordingly.

MI-05: HURON CITY. The boundary of the unit has been modified to account for shoreline erosion along Lake Huron to the east of Willow Creek.

MI-13: BIRDSONG BAY. The name of this unit has been changed from “Squaw Bay” to “Birdsong Bay” to reflect the new name of the underlying feature.

MI-21: ARCADIA LAKE. The boundary of the unit has been modified to account for natural changes along the shoreline of the peninsula located between Arcadia Lake and Lake Michigan.

MI-25: MINO-KWE POINT. The name of this unit has been changed from “Squaw Point” to “Mino-kwe Point” to reflect the new name of the underlying feature.

MI-40: GREEN ISLAND. The boundary of the unit has been modified to account for shoreline erosion along Lake Michigan at Point la Barbe.

MI-64: MINO-KWE JIIGIBIIB. The name of this unit has been changed from “Squaw Beach” to “Mino-kwe jiigibiik” to reflect the new name of the underlying feature.

Minnesota

The Service’s review found that the boundaries of Unit MN-01 (the only CBRS unit in Minnesota) do not need to

be modified due to changes from natural forces. The imagery that was used on the currently effective map is dated 2012. The imagery that was used for this review, and will be used for the revised map, is dated 2021.

Mississippi

The Service's review found that two of the seven CBRS units in Mississippi require changes due to natural forces. The imagery that was used on the currently effective maps is dated 2012. The imagery that was used for this review, and will be used for the revised maps, is dated 2021.

R02: DEER ISLAND. The western boundary of the unit has been modified to account for accretion at the western end of Deer Island.

R03: CAT ISLAND. The southern boundary of the eastern segment of the unit has been modified to account for accretion of the spit at the south end of Cat Island.

North Carolina

The Service made no changes to the 17 CBRS units in North Carolina, and revised maps have not been produced for this State. The imagery that was used on the currently effective maps is dated 2010, 2012, or 2014, depending on the unit. The imagery that was used for this review is dated 2020.

While no changes have been made to the CBRS boundaries in North Carolina at this time, future changes are warranted for the boundaries of Unit NC-03P, which were updated by Congress in 1999 through Public Law 106-116 to align with the boundaries of Cape Hatteras National Seashore at that time. However, there has been significant shoreline erosion along the Atlantic coast of Hatteras Island, particularly in the villages of Rodanthe, Waves, Avon, and Buxton, and the CBRS boundary is now hundreds of feet offshore in some places. Erosion is occurring at a rate of 2-4 meters per year in some areas.

In those places where the shoreline has eroded significantly, the boundary of Cape Hatteras National Seashore is the mean high-water line. Numerous structures may be located seaward of the mean high-water line due to erosion and may be on National Park Service owned property. Some of these structures have been deemed uninhabitable due to compromised septic systems and/or other issues. At the time of our review, the National Park Service was planning to conduct a boundary survey. As the survey was not completed before our 5-year review effort was completed, we have not made any boundary modifications at this time.

We plan to revisit the North Carolina CBRS units again with the next batch of 5-year review maps anticipated in 2023, and we invite Federal, State, and local officials to submit any pertinent data regarding shoreline erosion along Hatteras Island at this time. We will reassess the boundary of Unit NC-03P against the survey of the national seashore, more recent aerial and satellite imagery that we expect to be available in 2023, and any additional data that we receive from Federal, State, and local officials. We will also continue to monitor geomorphic change occurring in other areas in North Carolina, including the northwestern boundary of Unit L03AP (where geomorphic change is occurring very near to the CBRS boundary along Shackleford Banks).

Ohio

The Service's review found that 1 of the 10 CBRS units in Ohio requires changes due to natural forces. The imagery that was used on the currently effective maps is dated 2013 and 2014. The imagery that was used for this review, and will be used for the revised maps, is dated 2021.

OH-06: BAY POINT. The southern boundary of the unit has been modified to account for the southward accretion of Bay Point.

South Carolina

The Service's review found that 3 of the 10 CBRS units in South Carolina that are included in this review (Units M02, M03, M08, M09/M09P, M10, M13, SC-01, SC-03, and SC-10P) require changes due to natural forces. The imagery that was used on the currently effective maps is dated 2011, 2013, or 2015, depending on the unit. The imagery that was used for this review, and will be used for the revised maps, is dated 2021.

The remaining 13 South Carolina units are not included in this review, either because they were either comprehensively reviewed recently or they will be included in a more comprehensive review (beyond the scope of the 5-year review) at a later date, at which time the Service will also complete an assessment of changes necessary due to natural forces.

M03: PAWLEYS INLET. The southwestern boundary of the unit has been modified to account for natural changes in the wetlands.

M09: EDISTO COMPLEX. The coincident boundary between Units M09 and M09P has been modified to follow the current location of Jeremy Inlet. The landward boundary of the unit has been modified to reflect natural

changes in the configuration of the wetlands along the Townsend River.

M09P: EDISTO COMPLEX. The coincident boundary between Units M09 and M09P has been modified to follow the current location of Jeremy Inlet.

Texas

The Service's review found that 6 of the 35 CBRS units in Texas require changes due to natural forces. The imagery that was used on the currently effective maps is dated 2010. The imagery that was used for this review, and will be used for the revised maps, is dated 2020.

T03A: BOLIVAR PENINSULA. The boundary of the unit has been modified to reflect natural changes in the configuration of the wetlands on and around the Bolivar Peninsula.

T04: FOLLETS ISLAND. The boundary of the unit (a portion of which is coincident with Unit T04P) has been modified to reflect erosion along the shorelines of Mud Island and Moody Island.

T04P: FOLLETS ISLAND. The boundary of the unit (a portion of which is coincident with Unit T04) has been modified to reflect erosion along the shoreline of Moody Island.

T07: MATAGORDA PENINSULA. The coincident boundary between Unit T07 and T07P has been modified to account for natural changes at the mouth of Caney Creek.

T07P: MATAGORDA PENINSULA. The coincident boundary between Unit T07 and T07P has been modified to account for natural changes at the mouth of Caney Creek.

T12: BOCA CHICA. The boundary of the unit has been modified to account for natural changes along the shoreline of the Rio Grande.

Wisconsin

The Service's review found that three of the seven CBRS units in Wisconsin require changes due to natural forces. The imagery that was used on the currently effective maps is dated 2013. The imagery that was used for this review, and will be used for the revised maps, is dated 2020.

WI-03: PESHTIGO POINT. The southern boundary of the western segment of the unit has been modified to account for erosion and an increased lake level in Green Bay.

WI-04: DYERS SLOUGH. The eastern boundary of the unit has been modified to account for erosion and an increased lake level in Green Bay.

WI-07: FLAG RIVER. The western boundary of the unit has been modified to reflect natural changes in the

configuration of the wetlands at the mouth of the Flag River.

Request for Comments

CBRA requires consultation with the appropriate Federal, State, and local officials on the proposed CBRS boundary modifications to reflect changes that have occurred in the size or location of any unit as a result of natural forces (16 U.S.C. 3503(c)). We therefore invite interested Federal, State, and local officials to review and comment on the draft revised boundaries for Michigan, Minnesota, Mississippi, North Carolina, Ohio, South Carolina, Texas, and Wisconsin. The Service is specifically notifying the following stakeholders concerning the availability of the draft revised boundaries: (1) the Chair and Ranking Member of the House of Representatives Committee on Natural Resources; the Chair and Ranking Member of the Senate Committee on Environment and Public Works; and the members of the Senate and House of Representatives for the affected areas; (2) the governors of the affected areas; (3) State and local officials with floodplain management and/or land use responsibilities; and (4) Federal officials with knowledge of the coastal geomorphology within the project area.

Federal, State, and local officials may submit written comments and accompanying data as described in **ADDRESSES**, above. Comments regarding specific CBRS unit(s) should reference the appropriate unit number(s) and unit name(s). Please note that boundary modifications through the 5-year review process can only be made to reflect changes that have occurred in the size or location of any CBRS unit as a result of natural forces. Other requests for changes to the CBRS outside of the Service's administrative authorities (e.g., the removal of structures from a unit) will not be considered at this time. We must receive comments on or before the date listed above in **DATES**.

Following the close of the comment period, the Service will review all comments received on the draft revised boundaries; adjust the boundaries, as appropriate; prepare final revised maps; and publish a notice in the **Federal Register** to announce the availability of the final revised maps. The revised maps will take effect upon the date of publication of that notice in the **Federal Register**.

Availability of Draft Revised Coastal Barrier Resources System Boundaries and Related Information

The draft revised boundaries may be viewed in a web mapping application accessed from the Service's website at <https://www.fws.gov/project/cbrs-5-year-review>. A shapefile of the draft revised CBRS boundaries, which can be used with GIS software, is also available for download. The shapefile is best viewed using the base imagery to which the boundaries were drawn; the base imagery sources and dates are included in the metadata for the shapefile. The Service is not responsible for any misuse or misinterpretation of the shapefile.

Interested parties who are unable to access the draft revised boundaries or other information online may contact the individual identified in **FOR FURTHER INFORMATION CONTACT**, above, and reasonable accommodations will be made.

Gary Frazer,

Assistant Director for Ecological Services.

[FR Doc. 2022-25431 Filed 11-21-22; 8:45 am]

BILLING CODE 4333-15-P

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

[LLC0956000 L14400000.BJ0000 223]

Notice of Filing of Plats of Survey, Colorado

AGENCY: Bureau of Land Management, Interior.

ACTION: Notice of official filing.

SUMMARY: The plats of survey of the following described lands are scheduled to be officially filed in the Bureau of Land Management (BLM), Colorado State Office, Lakewood, Colorado, 30 calendar days from the date of this publication. The surveys, which were executed at the request of the U.S. Forest Service and the BLM, are necessary for the management of these lands.

DATES: Unless there are protests of this action, the plats described in this notice will be filed on December 22, 2022.

ADDRESSES: You may submit written protests to the BLM Colorado State Office, Cadastral Survey, 2850 Youngfield Street, Lakewood, CO 80215-7210.

FOR FURTHER INFORMATION CONTACT: David W. Ginther, Acting Chief Cadastral Surveyor for Colorado, telephone: (970) 826-5064; email:

dginther@blm.gov. Individuals in the United States who are deaf, deafblind, hard of hearing, or have a speech disability may dial 711 (TTY, TDD, or TeleBraille) to access telecommunications relay services. Individuals outside the United States should use the relay services offered within their country to make international calls to the point-of-contact in the United States.

SUPPLEMENTARY INFORMATION: The plat and field notes of the dependent resurvey and subdivision of sections in Township 27 South, Range 70 West, Sixth Principal Meridian, Colorado, were accepted on September 27, 2022.

The plat and field notes of the dependent resurvey and survey in Township 10 South, Range 103 West, Sixth Principal Meridian, Colorado, were accepted on October 14, 2022.

The supplemental plat of section 31 in Township 13 South, Range 86 West, Sixth Principal Meridian, Colorado, was accepted on November 4, 2022.

The supplemental plat of section 6 in Township 14 South, Range 86 West, Sixth Principal Meridian, Colorado, was accepted on November 4, 2022.

A person or party who wishes to protest any of the above surveys must file a written notice of protest within 30 calendar days from the date of this publication at the address listed in the **ADDRESSES** section of this notice. A statement of reasons for the protest may be filed with the notice of protest and must be filed within 30 calendar days after the protest is filed. If a protest against the survey is received prior to the date of official filing, the filing will be stayed pending consideration of the protest. A plat will not be officially filed until the day after all protests have been dismissed or otherwise resolved. Before including your address, phone number, email address, or other personal identifying information in your protest, please be aware that your entire protest, including your personal identifying information, may be made publicly available at any time. While you can ask us in your comment to withhold your personal identifying information from public review, we cannot guarantee that we will be able to do so.

(Authority: 43 U.S.C. chapter 3)

David W. Ginther,

Acting Chief Cadastral Surveyor.

[FR Doc. 2022-25412 Filed 11-21-22; 8:45 am]

BILLING CODE 4310-JB-P

DEPARTMENT OF THE INTERIOR**National Park Service**

[NPS-WASO-D-COS-POL-34564;
PPWODIREP0; PPMPSAS1Y.YP0000;
PX.XDIRE0039.00.1]

**Notice of the December 7 and 8, 2022,
Teleconference Meeting of the
Advisory Committee on Reconciliation
in Place Names**

AGENCY: National Park Service, Interior.

ACTION: Notice of teleconference meeting.

SUMMARY: In accordance with the Federal Advisory Committee Act of 1972, the National Park Service (NPS) is hereby giving notice that the Advisory Committee on Reconciliation in Place Names (Committee) will meet as noted below.

DATES: The teleconference meeting will be held on Wednesday and Thursday, December 7 and 8, 2022, from 2 p.m. until 6 p.m. (EASTERN). For instructions on registering to attend, submitting written material, or giving an oral presentation at the meeting, please see guidance under the **FOR FURTHER INFORMATION CONTACT** section.

FOR FURTHER INFORMATION CONTACT: For information concerning attending the Committee meeting, submitting written comments to the Committee, or requesting to address the Committee, contact Joshua Winchell, Staff Director for the Advisory Committee on Reconciliation in Place Names, Office of Policy, National Park Service, at reconciliation_committee@nps.gov or by telephone at (202) 513-7053.

Individuals in the United States who are deaf, deafblind, hard of hearing, or have a speech disability may dial 711 (TTY, TDD, or TeleBraille) to access telecommunications relay services. Individuals outside the United States should use the relay services offered within their country to make international calls to the point-of-contact in the United States.

SUPPLEMENTARY INFORMATION: The Committee has been established by authority of the Secretary of the Interior (Secretary) under 54 U.S.C. 100906 and is regulated by the Federal Advisory Committee Act.

Purpose of the Meeting: The Committee will receive briefings and discuss topics related to identifying existing federal land unit names and geographic feature names that may be considered derogatory and developing recommendations for potential

replacement names. The final agenda and briefing materials will be posted to the Committee's website prior to the meeting at <https://www.nps.gov/orgs/1892/advisory-committee-on-reconciliation-in-place-names.htm>.

The meeting is open to the public. Interested persons may choose to make oral comments at the meeting during the designated time for this purpose. Depending on the number of people wishing to comment and the time available, the amount of time for oral comments may be limited. Interested parties should contact the Staff Director for the Committee (see **FOR FURTHER INFORMATION CONTACT**) for advance placement on the public speaker list for this meeting. Members of the public may also choose to submit written comments by emailing them to reconciliation_committee@nps.gov. Due to time constraints during the meeting, the Committee is not able to read written public comments submitted into the record. Depending on the number of people who wish to speak and the time available, the time for individual comments may be limited. All comments will be made part of the public record and will be electronically distributed to all Committee members. Detailed minutes of the meeting will be available for public inspection within 90 days of the meeting.

Meeting Accessibility:

Please make requests in advance for sign language interpreter services, assistive listening devices, or other reasonable accommodations. We ask that you contact the person listed in the **FOR FURTHER INFORMATION CONTACT** section of this notice at least seven (7) business days prior to the meeting to give the Department of the Interior sufficient time to process your request. All reasonable accommodation requests are managed on a case-by-case basis.

Public Disclosure of Comments:

Before including your address, phone number, email address, or other personal identifying information in your comment, you should be aware that your entire comment—including your personal identifying information—may be made publicly available at any time. While you can ask us in your comment to withhold your personal identifying information from public review, we cannot guarantee that we will be able to do so.

Authority: 5 U.S.C. Appendix 2.

Alma Ripps,
Chief, Office of Policy.

[FR Doc. 2022-25379 Filed 11-21-22; 8:45 am]

BILLING CODE 4312-52-P

DEPARTMENT OF JUSTICE**Antitrust Division**

**Notice Pursuant to the National
Cooperative Research and Production
Act of 1993—Homeland Security
Technology Consortium**

Notice is hereby given that, on November 2, 2022, pursuant to section 6(a) of the National Cooperative Research and Production Act of 1993, 15 U.S.C. 4301 *et seq.* ("the Act"), Homeland Security Technology Consortium ("HSTech"), formerly Border Security Technology Consortium ("BSTC"), has filed written notifications simultaneously with the Attorney General and the Federal Trade Commission disclosing changes in its membership. The notifications were filed for the purpose of extending the Act's provisions limiting the recovery of antitrust plaintiffs to actual damages under specified circumstances. Specifically, Bounce Imaging, Buffalo, NY; Consolidated Resource Imaging LLC (CRI), Grand Rapids, MI; InfiNetix, Arnold, MD; LiveView Technologies, Orem, UT; Mainstream Engineering, Rockledge, FL; Mission Driven Research, Inc., Huntsville, AL; T-Rex Solutions LLC, Greenbelt, MD; and ZeroEyes, Inc., Conshohocken, PA, have been added as parties to this venture.

No other changes have been made in either the membership or planned activity of the group research project. Membership in this group research project remains open, and HSTech intends to file additional written notifications disclosing all changes in membership.

On May 30, 2012, HSTech (formerly BSTC) filed its original notification pursuant to Section 6(a) of the Act. The Department of Justice published a notice in the **Federal Register** pursuant to Section 6(b) of the Act on June 18, 2012 (77 FR 36292).

The last notification was filed with the Department on May 2, 2022. A notice was published in the **Federal Register** pursuant to section 6(b) of the Act on May 31, 2022 (87 FR 32460).

Suzanne Morris,

Deputy Director, Civil Enforcement
Operations, Antitrust Division.

[FR Doc. 2022-25450 Filed 11-21-22; 8:45 am]

BILLING CODE P

DEPARTMENT OF LABOR**Employee Benefits Security Administration**

[Prohibited Transaction Exemption 2022–04; Exemption Application No. D–12048]

Exemption From Certain Prohibited Transaction Restrictions Involving the Children's Hospital of Philadelphia Pension Plan for Union-Represented Employees Located in Philadelphia, PA

AGENCY: Employee Benefits Security Administration, Labor.

ACTION: Notice of exemption.

SUMMARY: This document contains a notice of exemption issued by the Department of Labor (the Department) from certain of the prohibited transaction restrictions of the Employee Retirement Income Security Act of 1974 (ERISA or the Act) and/or the Internal Revenue Code of 1986 (the Code). This exemption permits the sale (the Sale) of certain illiquid private fund interests (the Interests) by the Children's Hospital of Philadelphia Pension Plan for Union-Represented Employees (the Plan or the Applicant) to the Children's Hospital of Philadelphia Foundation (the Foundation).

FOR FURTHER INFORMATION CONTACT: Mr. Joseph Brennan of the Department at (202) 693–8456. (This is not a toll-free number.)

SUPPLEMENTARY INFORMATION: The Applicant requested an individual exemption pursuant to ERISA section 408(a) in accordance with the procedures set forth in 29 CFR part 2570, subpart B (76 FR 66637, 66644, October 27, 2011).

On March 9, 2022, the Department published a notice of proposed exemption in the **Federal Register** that would permit the Sale of the Interests by the Plan to the Foundation, provided certain conditions are met.¹

After considering the entire record developed in connection with the Applicant's exemption application, including two comment letters discussed below, the Department has determined to grant the exemption subject to the new definitions section and the conditions described below. The exemption only provides the relief specified in the exemption text and does not provide relief from violations of any law other than the prohibited transaction provisions of ERISA expressly stated herein.

The Department makes the requisite findings under ERISA section 408(a)

that the exemption is: (1) administratively feasible, (2) in the interest of the plan and its participants and beneficiaries, and (3) protective of the rights of the Plan's participants and beneficiaries, if all of the exemption conditions are met. Accordingly, affected parties should be aware that the conditions incorporated in this exemption are, individually and taken as a whole, necessary for the Department to grant the relief requested by the Applicant. Absent these or similar conditions, the Department would not have granted this exemption.

Background

As discussed in further detail in the proposed exemption, the Plan owns 23 private fund limited partnership interests and one illiquid "side pocket" portion of an original hedge fund investment (the Interests). The Interests include investments in private equity funds, real estate funds, and natural resource funds. The Applicant represents that the Plan originally invested in the Interests because each Interest provided significant risk adjusted rate of return potential and appropriate investment diversification. As of October 1, 2021, the Interests represented approximately 8.5% of the Plan's assets, with fair market values ranging from \$0 to \$990,321.

The Plan intends to improve Plan liquidity and diversification by selling the Interests. As confirmed by Newport Trust Company (Newport), the independent fiduciary engaged to represent the Plan, sales of the Interests to an unrelated third party on the open market would likely be for less than book value. According to Newport, such sales for the Interests' fair market value would require approval from the respective general partner of each Interest and would likely result in the plan receiving approximately 15 percent less than the cash equivalent of book value. Rather than sell the Interests for less than book value, the Applicant requested an exemption to permit the Plan to sell the Interests at full book value to the Foundation, a party in interest with respect to the Plan.² An exemption is necessary because the Sale is prohibited under ERISA and the Code.

On March 9, 2022, the Department proposed an exemption that would permit the Plan to sell the Interests to the Foundation. The exemption requires a prudently appointed and qualified

independent fiduciary, Newport, to protect and promote the interests of Plan participants and beneficiaries in the transaction. The exemption also contains protective conditions, including a requirement that Newport represent the Plan's interests for all purposes with respect to the Sale, and a requirement that the Plan not pay any commissions, fees, or other expenses associated with the Sale.

The Department finds that the favorable terms of the Sale together with the protective conditions included herein are appropriately protective of, and in the interest of the Plan and its participants and beneficiaries.

Written Comments Received

In the proposed exemption, the Department invited all interested persons to submit written comments and/or requests for a public hearing with respect to the notice of proposed exemption.

The Department received one comment letter from Newport and another from the Applicant. The Department did not receive any requests for a public hearing. Presented below is a discussion of both comment letters.

Comments From Newport

Section II (c) of the proposed exemption states that: "The Sale price for each Interest will be the fair market value of the Interest as of the date of the Sale, as determined by the Independent Fiduciary, based upon an updated Independent Appraisal Report prepared by the Independent Appraiser that values the Interest as of the date of the Sale."

In its comment letter, Newport states that it evaluated the Sale of the Interests by the Plan to the Foundation based upon the assumption that the Plan would receive the greater of: (1) the fair market value of each Interest as of the date of the Sale, as determined by Newport, based upon a qualified independent appraisal by SB Advisors LLC (SB Advisors); or (2) the book value of each Interest, as determined by the general partner of each Interest (less any distributions and plus any contributions made between the valuation date and the Sale). Newport states that the book value of the Interests exceeded their fair market value by \$2,114,073 based on the valuation report prepared by SB Advisors dated May 24, 2021. Newport represents that it referred to this favorable pricing, among other factors, when it concluded that the terms and conditions of the Sale were favorable to the Plan and its participants.

Newport recommends that the Department add an exemption condition

¹ 87 FR 13324, March 9, 2022.

² The Foundation's relationship to the Plan Sponsor is that the Foundation supports the operations and funding of the Plan Sponsor, but the two entities do not have any ownership interests in each other.

that would require CHOP to make a voluntary cash contribution to the Plan in the amount equal to the difference (if any) between: (1) the book value of each of the Interests as determined by the general partner of each Interest as reflected on the most recent valuation statement of the Interest immediately before the Sale (less any distributions and plus any contributions made between the valuation date and the sale), and (2) the fair market value of each Interest as of the date of the Sale as determined by Newport based upon a qualified independent appraisal by SB Advisors.

Department's Response: The Department agrees with Newport's recommendation that the Plan receives the greater of fair market value or full book value for the Interests. However, the Department has determined that the Sale of the Interests must be for the greater of book value or fair market value rather than fair market value plus a subsequent cash contribution. Therefore, the Department has amended section II(c) to state, "The Sale price for each Interest will equal the greater of: (1) the fair market value of each Interest as of the date of the Sale, as determined by Newport, based upon a qualified independent appraisal by SB Advisors LLC (SB Advisors); or (2) the book value of each Interest, as determined by the general partner of each Interest as reflected on the most recent valuation statement of the Interest immediately before the Sale (less any distributions made from the Interest to the Plan and plus any contributions made by the Plan to the Interests between the valuation date and the Sale)."

Comments From the Applicant

In its comment letter, the Applicant requests the Department to incorporate the following factual corrections into the exemption: (1) the full name of the Committee is "The Pension Fiduciary Committee of the Children's Hospital of Philadelphia;" (2) as of April 29, 2022, the duration of the Plan's investment in the Interests is 11–17 years, rather than 7–18 years as stated in the proposed exemption; and (3) the Foundation's relationship to the Plan Sponsor is that the Foundation supports the operations and funding of the Plan Sponsor, but the two entities are not connected on the basis of ownership (and more specifically, the Foundation does not own the Plan Sponsor).

Department's Response: The Department acknowledges and accepts the Applicant's factual corrections to the proposed exemption.

The complete application file (D–12048) for this exemption is available

for public inspection in the Public Disclosure Room of the Employee Benefits Security Administration, Room N–1515, U.S. Department of Labor, 200 Constitution Avenue NW, Washington, DC 20210. For a more complete statement of the facts and representations supporting the Department's decision to grant this exemption, please refer to the notice of proposed exemption published on March 9, 2022, at 87 FR 13324.

General Information

The attention of interested persons is directed to the following:

(1) The fact that a transaction is the subject of an exemption under ERISA section 408(a) does not relieve a fiduciary or other party in interest from certain requirements of other ERISA provisions, including any prohibited transaction provisions to which the exemption does not apply and the general fiduciary responsibility provisions of ERISA section 404, which, among other things, require a fiduciary to discharge their duties respecting the plan prudently and solely in the interest of the plan's participants and beneficiaries.

(2) As required by ERISA section 408(a), the Department hereby finds that the exemption is: (a) administratively feasible; (b) in the interests of the affected plan and its participants and beneficiaries; and (c) protective of the rights of the plan's participants and beneficiaries.

(3) This exemption is supplemental to, and not in derogation of, any other ERISA provisions, including statutory or administrative exemptions and transitional rules. Furthermore, the fact that a transaction is subject to an administrative or statutory exemption is not dispositive of determining whether the transaction is in fact a prohibited transaction.

(4) The availability of this exemption is subject to the express condition that the material facts and representations contained in the application accurately describe all material terms of the transactions that are the subject of the exemption.

Accordingly, the Department grants the following exemption under the authority of ERISA section 408(a) and in accordance with the procedures set forth in 29 CFR part 2570, subpart B (76 FR 66637, 66644, October 27, 2011):

Exemption

Section I. Definitions

(a) "CHOP" means The Children's Hospital of Philadelphia, the Plan sponsor of the Children's Hospital of

Philadelphia Pension Plan for Union-Represented Employees.

(b) "The Foundation" means the Children's Hospital of Philadelphia Foundation.

(c) The term "Independent Appraiser" means an individual or entity meeting the definition of a "Qualified Independent Appraiser" under Department Regulation 29 CFR 2570.31(i) retained to determine, on behalf of the Plan, the fair market value of the Interests as of the date of the Sale and who:

(1) Is not CHOP or the Foundation or an affiliate of CHOP or the Foundation and does not hold an ownership interest in CHOP, the Foundation or affiliates of CHOP or the Foundation;

(2) Is independent of and is not related to any party to the exemption transaction, including CHOP, the Foundation, and the Independent Fiduciary, as defined below;

(3) Has acknowledged in writing that it has appropriate technical training or experience to perform the services contemplated by the exemption;

(4) Has not entered into any agreement or instrument that violates the prohibitions on exculpatory provisions in ERISA section 410 or the Department's regulation relating to indemnification of fiduciaries at 29 CFR 2509.75–4;

(5) For purposes of this definition, no organization or individual may serve as Independent Appraiser for any fiscal year if the gross income received by such organization or individual from CHOP, the Foundation, and affiliates of CHOP and the Foundation for that fiscal year exceeds two percent of such organization's or individual's gross income from all sources for the prior fiscal year. This provision also applies to a partnership or corporation of which such organization or individual is an officer, director, or 10 percent or more partner or shareholder and includes as gross income amounts received as compensation for services provided as an independent fiduciary under any prohibited transaction exemption granted by the Department;

(6) No organization or individual that is an Independent Appraiser and no partnership or corporation of which such organization or individual is an officer, director, or ten percent or more partner or shareholder may acquire any property from, sell any property to, or borrow any funds from CHOP, the Foundation, or affiliates of CHOP or the Foundation while the individual serves as an Independent Appraiser. This prohibition would continue for a period of six months after the party ceases to be an Independent Appraiser; and

(7) In the event a successor Independent Appraiser is appointed to represent the interests of the Plan with respect to the subject transactions, no time should elapse between the resignation or termination of the former Independent Appraiser and the appointment of the successor Independent Appraiser;

(d) The term "Independent Fiduciary" means a person who:

(1) Is not CHOP or the Foundation or an affiliate of CHOP or the Foundation and does not hold an ownership interest in CHOP, the Foundation or affiliates of CHOP or the Foundation;

(2) Was not a fiduciary with respect to the Plan before its appointment to serve as the Independent Fiduciary;

(3) Has acknowledged in writing that:

(i) It is a fiduciary and has agreed not to participate in any decision with respect to any transaction in which it has an interest that might affect its best judgment as a fiduciary; and

(ii) Has appropriate technical training or experience to perform the services contemplated by the exemption;

(4) Has not entered into any agreement or instrument that violates the prohibitions on exculpatory provisions in ERISA section 410 or the Department's regulation relating to indemnification of fiduciaries at 29 CFR 2509.75-4;

(5) For purposes of this definition, no organization or individual may serve as Independent Fiduciary for any fiscal year if the gross income received by such organization or individual from CHOP, the Foundation, and affiliates of CHOP and the Foundation for that fiscal year exceeds two percent of such organization's or individual's gross income from all sources for the prior fiscal year. This provision also applies to a partnership or corporation of which such organization or individual is an officer, director, or 10 percent or more partner or shareholder and includes as gross income amounts received as compensation for services provided as an independent fiduciary under any prohibited transaction exemption granted by the Department;

(6) No organization or individual that is an Independent Fiduciary and no partnership or corporation of which such organization or individual is an officer, director or ten percent or more partner or shareholder may acquire or commit to acquire any property from, sell or commit to sell any property to, borrow or commit to borrow any funds from, or lend or commit to lend any assets to CHOP, the Foundation, or affiliates of CHOP or the Foundation while the individual serves as an Independent Fiduciary. This prohibition

would continue for a period of six months after either: (i) the party ceases to be an Independent Fiduciary, or (ii) the Independent Fiduciary negotiates on behalf of the Plan during the period that such organization or the individual serves as an Independent Fiduciary; and

(7) In the event a successor Independent Fiduciary is appointed to represent the interests of the Plan with respect to the subject transactions, no time should elapse between the resignation or termination of the former Independent Fiduciary and the appointment of the successor Independent Fiduciary;

(e) The term "Interests" means certain private fund limited partnership interests and one illiquid side pocket portion of an original hedge fund investment to be sold by the Children's Hospital of Philadelphia Pension Plan for Union-Represented Employees to the Foundation. The Interests consist of 18 funds that are spread among 14 managers and have varying durations. The Plan's investment duration in the Interests ranges from 11-17 years.

(f) The term "Plan" means the Children's Hospital of Philadelphia Pension Plan for Union-Represented Employees.

Section II. Covered Transactions

The restrictions of ERISA sections 406(a)(1)(A) and (D), and 406(b)(1) and (b)(2), and the sanctions resulting from the application of Code section 4975, by reason of Code sections 4975(c)(1)(A), (D) and (E) shall not apply to the sale (the Sale) of certain illiquid private fund interests (the Interest(s)) by the Children's Hospital of Philadelphia Pension Plan for Union-Represented Employees (the Plan or the Applicant) to the Children's Hospital of Philadelphia Foundation (the Foundation) where the Sale price for each Interest is the greater of: (1) the fair market value of each Interest as of the date of the Sale, as determined by Newport Trust Company (Newport), based upon a qualified independent appraisal by SB Advisors LLC (SB Advisors); or (2) the book value of each Interest, as determined by the general partner of each Interest as reflected on the most recent valuation statement of the Interest immediately before the Sale (less any distributions made from the Interest to the Plan and plus any contributions made by the Plan to the Interest between the valuation date and the Sale). In order to receive such relief, the Conditions in Section III must be met in conformance with the Definitions set forth in Section I.

Section III. Conditions

(a) The Sale of each Interest is a one-time transaction for cash;

(b) The terms and conditions of the Sale are at least as favorable to the Plan as those the Plan could obtain in an arm's-length transaction with an unrelated third party;

(c) The Sale price for each Interest will equal the greater of: (1) the fair market value of each Interest as of the date of the Sale, as determined by Newport, based upon a qualified independent appraisal by SB Advisors; or (2) the book value of each Interest, as determined by the general partner of each Interest as reflected on the most recent valuation statement of the Interest immediately before the Sale (less any distributions made from the Interest to the Plan and plus any contributions made by the Plan to the Interest between the valuation date and the Sale).

(d) The Foundation assumes any remaining capital commitments in connection with the Interests;

(e) The Plan pays no commissions, fees, or other expenses in connection with the Sale;

(f) The Independent Fiduciary:

(1) Represents the Plan's interests for all purposes with respect to the Sale;

(2) Determines that the Sale is in the interests of, and protective of, the Plan and its participants and beneficiaries;

(3) Determines that the Sale price for the Interests is protective of and in the interests of the Plan;

(4) Reviews and approves the terms and conditions of the Sale;

(5) Independently and prudently engages the Independent Appraiser for the Sale;

(6) Reviews the Independent Appraisal Report, confirms that the underlying methodology is reasonable and accurate and that the Independent Appraiser has reasonably determined the fair market valuation of the Interests in accordance with professional standards;

(7) Ensures that the Independent Appraiser renders an updated fair market valuation of the Interests as of the date of the Sale that includes a separate assessment regarding the likelihood that any Interest reported as having no value in the appraisal report may receive trailing distributions. The Independent Appraiser must consider this likelihood when valuing any Interest and address the extent to which this likelihood affects the Interest's value in its report;

(8) Determines whether it is prudent for the Plan to proceed with the Sale;

(9) Has not and will not enter into any agreement or instrument that violates ERISA Section 410;³

(10) Confirms that each condition of the exemption has been met; and

(11) Submits a written report to the Department not later than 90 days after the Sale has been completed demonstrating that each exemption condition has been met. The written report must include the Independent Fiduciary's determinations regarding whether any Interest is likely to receive trailing distributions and the extent to which any anticipated trailing distributions increased the Interest's value.

(g) The Plan does not bear the costs of: (1) the exemption application; (2) obtaining the exemption; nor (3) the Independent Fiduciary or Independent Appraiser's fees;

(h) The Foundation receives written consent from each Fund manager to purchase the Interests from the Plan before engaging in the Sale of the respective Interests;

(i) The Sale is not part of an agreement, arrangement, or understanding designed to benefit CHOP or the Foundation; and

(j) All the material facts and representations set forth in the Summary of Facts and Representations are true and accurate at all times.

Effective Date: This exemption will become effective on the date that this grant notice is published in the **Federal Register**.

Signed at Washington, DC.

George Christopher Cosby,

*Director, Office of Exemption Determinations,
Employee Benefits Security Administration,
U.S. Department of Labor.*

[FR Doc. 2022-25378 Filed 11-21-22; 8:45 am]

BILLING CODE 4510-29-P

DEPARTMENT OF LABOR

Occupational Safety and Health Administration

[Docket No. OSHA-2007-0042]

TUV Rheinland of North America, Inc.: Application for Expansion of Recognition

AGENCY: Occupational Safety and Health Administration (OSHA), Labor.

ACTION: Notice.

SUMMARY: In this notice, OSHA announces the application of TUV Rheinland of North America, Inc., for expansion of the scope of recognition as a Nationally Recognized Testing Laboratory (NRTL) and presents the agency's preliminary finding to grant the application.

DATES: Submit comments, information, and documents in response to this notice, or requests for an extension of time to make a submission, on or before December 7, 2022.

ADDRESSES: Comments may be submitted as follows:

Electronically: You may submit comments, including attachments, electronically at <http://www.regulations.gov>, the Federal eRulemaking Portal. Follow the online instructions for submitting comments.

Facsimile: If your comments, including attachments, are not longer than 10 pages, you may fax them to the OSHA Docket Office at (202) 693-1648.

Docket: To read or download comments or other material in the docket, go to <https://www.regulations.gov>. All documents in the docket (including this **Federal Register** notice) are listed in the <https://www.regulations.gov> index; however, some information (e.g., copyrighted material) is not publicly available to read or download through the website. All submissions, including copyrighted material, are available for inspection through the OSHA Docket Office.

Instructions: All submissions must include the agency name and the OSHA docket number (OSHA-2007-0042). OSHA places comments and other materials, including any personal information, in the public docket without revision, and these materials will be available online at <http://www.regulations.gov>. Therefore, the agency cautions commenters about submitting statements they do not want made available to the public, or submitting comments that contain personal information (either about themselves or others) such as Social Security numbers, birth dates, and medical data. For further information on submitting comments, see the "Public Participation" heading in the section of this notice titled **SUPPLEMENTARY INFORMATION**.

Extension of comment period: Submit requests for an extension of the comment period on or before December 7, 2022 to the Office of Technical Programs and Coordination Activities, Directorate of Technical Support and Emergency Management, Occupational Safety and Health Administration, U.S. Department of Labor, 200 Constitution

Avenue NW, Room N-3653, Washington, DC 20210, or by fax to (202) 693-1644.

FOR FURTHER INFORMATION CONTACT: Information regarding this notice is available from the following sources:

Press inquiries: Contact Mr. Frank Meilinger, Director, OSHA Office of Communications, U.S. Department of Labor, telephone: (202) 693-1999; email: meilinger.francis2@dol.gov.

General and technical information: Contact Mr. Kevin Robinson, Director, Office of Technical Programs and Coordination Activities, Directorate of Technical Support and Emergency Management, Occupational Safety and Health Administration, U.S. Department of Labor, phone: (202) 693-2110 or email: robinson.kevin@dol.gov.

SUPPLEMENTARY INFORMATION:

I. Notice of the Application for Expansion

OSHA is providing notice that TUV Rheinland of North America, Inc. (TUVRNA), is applying for an expansion of current recognition as a NRTL. TUVRNA requests the addition of one test standard to the NRTL scope of recognition.

OSHA recognition of a NRTL signifies that the organization meets the requirements specified in 29 CFR 1910.7. Recognition is an acknowledgment that the organization can perform independent safety testing and certification of the specific products covered within the scope of recognition. Each NRTL's scope of recognition includes (1) the type of products the NRTL may test, with each type specified by the applicable test standard and (2) the recognized site(s) that has/have the technical capability to perform the product-testing and product-certification activities for test standards within the NRTL's scope. Recognition is not a delegation or grant of government authority; however, recognition enables employers to use products approved by the NRTL to meet OSHA standards that require product testing and certification.

The agency processes applications by a NRTL for initial recognition, as well as for an expansion or renewal of recognition, following requirements in Appendix A to 29 CFR 1910.7. This appendix requires that the agency publish two notices in the **Federal Register** in processing an application. In the first notice, OSHA announces the application and provides the preliminary finding. In the second notice, the agency provides the final decision on the application. These notices set forth the NRTL's scope of recognition or modifications of that

³ ERISA section 410 generally provides that any provision in an agreement or instrument that purports to relieve a fiduciary for responsibility or liability for any responsibility, obligation, or duty under Part I of Title I of ERISA is void against public policy.

scope. OSHA maintains an informational web page for each NRTL, including TUVRNA, which details that NRTL's scope of recognition. These pages are available from the OSHA website at <http://www.osha.gov/dts/otpcanrtl/index.html>.

TUVRNA currently has eight facilities (sites) recognized by OSHA for product testing and certification, with the headquarters located at: TUV Rheinland of North America, Inc., 12 Commerce Road, Newtown, Connecticut 06470. A complete list of TUVRNA sites recognized by OSHA is available at <https://www.osha.gov/nationally-recognized-testing-laboratory-program/tuv>.

II. General Background on the Application

TUVRNA submitted an application, dated February 22, 2022 (OSHA–2007–0042–0060), to expand recognition as a NRTL to include one additional test standard. OSHA staff performed a detailed analysis of the application packet and reviewed other pertinent information. OSHA did not perform any on-site reviews in relation to this application.

Table 1 shows the test standard found in TUVRNA's application for expansion for testing and certification of products under the NRTL Program.

TABLE 1—PROPOSED APPROPRIATE TEST STANDARD FOR INCLUSION IN TUVRNA'S NRTL SCOPE OF RECOGNITION

Test standard	Test standard title
UL 2580	Standard for Batteries for Use in Electric Vehicles.

III. Preliminary Finding on the Application

TUVRNA submitted an acceptable application for expansion of the scope of recognition. OSHA's review of the application file and pertinent documentation preliminarily indicates that TUVRNA can meet the requirements prescribed by 29 CFR 1910.7 for expanding its recognition to include the addition of the one test standard shown in Table 1, above, for NRTL testing and certification. This preliminary finding does not constitute an interim or temporary approval of TUVRNA's application.

OSHA seeks public comment on this preliminary determination.

IV. Public Participation

OSHA welcomes public comment as to whether TUVRNA meets the requirements of 29 CFR 1910.7 for

expansion of recognition as a NRTL. Comments should consist of pertinent written documents and exhibits.

Commenters needing more time to comment must submit a request in writing, stating the reasons for the request by the due date for comments. OSHA will limit any extension to 10 days unless the requester justifies a longer time period. OSHA may deny a request for an extension if it is not adequately justified.

To review copies of the exhibits identified in this notice, as well as comments submitted to the docket, contact the Docket Office, Occupational Safety and Health Administration, U.S. Department of Labor. These materials also are generally available online at <https://www.regulations.gov> under Docket No. OSHA–2007–0042 (for further information, see the “Docket” heading in the section of this notice titled ADDRESSES).

OSHA staff will review all comments to the docket submitted in a timely manner. After addressing the issues raised by these comments, staff will make a recommendation to the Assistant Secretary of Labor for Occupational Safety and Health on whether to grant TUVRNA's application for expansion of the scope of recognition. The Assistant Secretary will make the final decision on granting the application. In making this decision, the Assistant Secretary may undertake other proceedings prescribed in Appendix A to 29 CFR 1910.7.

OSHA will publish a public notice of the final decision in the **Federal Register**.

IV. Authority and Signature

James S. Frederick, Deputy Assistant Secretary of Labor for Occupational Safety and Health, 200 Constitution Avenue NW, Washington, DC 20210, authorized the preparation of this notice. Accordingly, the agency is issuing this notice pursuant to 29 U.S.C. 657(g)(2), Secretary of Labor's Order No. 8–2020 (85 FR 58393; Sept. 18, 2020), and 29 CFR 1910.7.

Signed at Washington, DC, on November 15, 2022.

James S. Frederick,

Deputy Assistant Secretary of Labor for Occupational Safety and Health.

[FR Doc. 2022–25377 Filed 11–21–22; 8:45 am]

BILLING CODE 4510–26–P

NATIONAL ARCHIVES AND RECORDS ADMINISTRATION

[NARA–2023–008]

Advisory Committee on the Records of Congress; Meeting

AGENCY: National Archives and Records Administration (NARA).

ACTION: Notice of Federal Advisory Committee meeting.

SUMMARY: We are announcing an upcoming meeting of the Advisory Committee on the Records of Congress in accordance with the Federal Advisory Committee Act. The committee advises NARA on the full range of programs, policies, and plans for the Center for Legislative Archives in the Office of Legislative Archives, Presidential Libraries, and Museum Services (LPM).

DATES: The meeting will be on December 5, 2022, from 10 a.m. to 12 p.m.

ADDRESSES: The meeting will take place at the U.S. Government Publishing Office, Carl Hayden Room (C–808), 732 North Capitol Street NW, Washington, DC 20401.

SUPPLEMENTARY INFORMATION: The meeting is open to the public. Due to restricted access at the U.S. Government Publishing Office, members of the public who wish to attend the Advisory Committee on the Records of Congress meeting are required to register for access to the meeting no later than Monday, November 28, 2022, by emailing the Office of Art and Archives at archives@mail.house.gov with your name and contact information.

Due to building security measures, attendees will be screened before entry and cannot bring certain items into the building.

Screening

- Except those with documented medical conditions, everyone will walk through the stationary magnetometer.
- Prior to entering the metal detector archway, have the entrant remove all metallic carry items in their possession, within their pockets, exterior covering and on their person.
- This includes jewelry of significant bulk, and jewelry capable of triggering an alert that disrupts the flow of pedestrian traffic by putting an undue burden on the security screening process.

Prohibited Items

- Alcoholic Beverages
- Drugs and Drug paraphernalia
- Contraband (Dangerous weapons, *e.g.*, guns, knives, with blades in excess of

2½ inches, flammable liquids, incendiary devices, mace, pepper spray, explosive devices; components, improvised IEDs, billy clubs, brass knuckles, night sticks, etc.)

- Unauthorized Equipment
- Solicitor bills or flyers
- Cellular telephones are authorized into GPO; however, photography is only authorized with prior written consent (from Security Services/ Public Relations)

Agenda

- (1) Chair's Opening Remarks—Clerk of the U.S. House of Representatives
- (2) Recognition of Co-chair—Secretary of the U.S. Senate
- (3) Recognition of the Acting Archivist of the United States
- (4) Approval of the minutes of the last meeting
- (5) House Archivist's report
- (6) Senate Archivist's report
- (7) Center for Legislative Archives update
- (8) Other current issues and new business

Tasha Ford,

Committee Management Officer.

[FR Doc. 2022–25386 Filed 11–21–22; 8:45 am]

BILLING CODE 7515–01–P

NATIONAL CREDIT UNION ADMINISTRATION

Submission for OMB Review; Comment Request

AGENCY: National Credit Union Administration (NCUA).

ACTION: Notice.

SUMMARY: The National Credit Union Administration (NCUA) will submit the following information collection requests to the Office of Management and Budget (OMB) for review and clearance in accordance with the Paperwork Reduction Act of 1995, on or after the date of publication of this notice.

DATES: Comments should be received on or before December 22, 2022 to be assured of consideration.

ADDRESSES: Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to www.reginfo.gov/public/do/PRAMain. Find this particular information collection by selecting “Currently under 30-day Review—Open for Public Comments” or by using the search function.

FOR FURTHER INFORMATION CONTACT: Copies of the submission may be

obtained by contacting Dawn Wolfgang at (703) 548–2279, emailing PRAComments@ncua.gov, or viewing the entire information collection request at www.reginfo.gov.

SUPPLEMENTARY INFORMATION:

OMB Number: 3133–0059.

Type of Review: Extension of a currently approved collection.

Title: Supervisory Committee Audits and Verifications, 12 CFR 715.

Abstract: Title 12 CFR part 715 prescribes the responsibilities of the supervisory committee to obtain an audit of the credit union and verification of member accounts as outlined in Section 115 of the Federal Credit Union Act, 12 U.S.C. 1761d. A supervisory committee audit is required at least once every calendar year covering the period since the last audit and to conduct a verification of members' accounts not less frequently than once every two years. The information is used by both the credit union and the NCUA to ensure through audit testing that the credit union's assets, liabilities, equity, income, and expenses exist, are properly valued, controlled and meet ownership, disclosure and classification requirements of sound financial reporting.

Affected Public: Private sector: not-for-profit institutions.

Estimated Total Annual Burden Hours: 12,549.

OMB Number: 3133–0146.

Type of Review: Extension of a currently approved collection.

Title: Production of Nonpublic Records and Testimony of Employees in Legal Proceedings.

Abstract: Title 12 CFR part 792, subpart C requires anyone requesting NCUA non-public records for use in legal proceedings, or similarly the testimony of NCUA personnel, to provide NCUA with information regarding the requester's grounds for the request. This process is also known as a “Touhy Request”. The information collected will help NCUA decide whether to release non-public records or permit employees to testify in legal proceedings. NCUA regulations also require an entity or person in possession of NCUA records to notify the NCUA upon receipt of a subpoena for those records. The NCUA requires this notice to protect its records and, when necessary, intervene in litigation or file an objection to the disclosure of its confidential information in the appropriate court or tribunal.

Affected Public: Individuals or households.

Estimated Total Annual Burden Hours: 100.

By Melane Conyers-Ausbrooks, Secretary of the Board, the National Credit Union Administration, on November 17, 2022.

Dated: November 17, 2022.

Dawn D. Wolfgang,

NCUA PRA Clearance Officer.

[FR Doc. 2022–25446 Filed 11–21–22; 8:45 am]

BILLING CODE 7535–01–P

NATIONAL SCIENCE FOUNDATION

Sunshine Act Meetings

The National Science Board's (NSB) Committee on Oversight hereby gives notice of the scheduling of a videoconference meeting for the transaction of National Science Board business pursuant to the National Science Foundation Act and the Government in the Sunshine Act.

TIME AND DATE: Monday, November 28, 2022, from 2:30–3:00 p.m. EST.

PLACE: This meeting will be held by videoconference through the National Science Foundation.

STATUS: Open.

MATTERS TO BE CONSIDERED: The agenda of the meeting is: Committee Chair's opening remarks; Office of the Inspector General (OIG) update; and Chief Financial Officer (CFO) update.

CONTACT PERSON FOR MORE INFORMATION:

Point of contact for this meeting is: (Chris Blair, cblair@nsf.gov), 703/292–7000. Members of the public can observe this meeting through a YouTube livestream. Please consult the NSB website for the link.

Christopher Blair,

Executive Assistant to the National Science Board Office.

[FR Doc. 2022–25645 Filed 11–18–22; 4:15 pm]

BILLING CODE 7555–01–P

NATIONAL TRANSPORTATION SAFETY BOARD

Sunshine Act Meeting

TIME AND DATE: 9:30 a.m. EDT, December 13, 2022.

PLACE: Virtual.

STATUS: The one item may be viewed by the public through webcast only.

MATTERS TO BE CONSIDERED:

69049 Safety Research Report—Alcohol, Other Drug, and Multiple Drug Use Among Drivers.

CONTACT PERSON FOR MORE INFORMATION:

Candi Bing at (202) 590–8384 or by email at bingc@ntsb.gov.

Media Information Contact: Sarah Sulick by email at Sarah.Sulick@ntsb.gov at (202) 314-6100.

This meeting will take place virtually. The public may view it through a live or archived webcast by accessing a link under "Upcoming Events" on the NTSB home page at www.nts.gov.

There may be changes to this event due to the evolving situation concerning the novel coronavirus (COVID-19). Schedule updates, including weather-related cancellations, are also available at www.nts.gov.

The National Transportation Safety Board is holding this meeting under the Government in the Sunshine Act, 5 U.S.C. 552(b).

Dated: November 18, 2022.

LaSean R. McCray,

Assistant Federal Register Liaison Officer.

[FR Doc. 2022-25637 Filed 11-18-22; 4:15 pm]

BILLING CODE 7533-01-P

NUCLEAR REGULATORY COMMISSION

[Docket No. 11006380; NRC-2022-0195]

Perma-Fix Northwest Richland, Inc.

AGENCY: Nuclear Regulatory Commission.

ACTION: Export license application; opportunity to provide comments, request a hearing, and petition for leave to intervene.

SUMMARY: On October 17, 2022, the U.S. Nuclear Regulatory Commission (NRC) received an application to amend an export license (XW027/01), from Perma-Fix Northwest Richland, Inc. (PFNW), authorizing the export of low-level radioactive waste to Eckert and Ziegler Nuclitech GmbH located in Germany. The request seeks the NRC's approval to amend an existing license authorizing the export of radioactive waste to Germany. The NRC is providing notice of the opportunity to comment, request a hearing, and petition to intervene on PFWN's application.

DATES: Submit comments by December 22, 2022. A request for a hearing or a petition for leave to intervene must be filed by December 22, 2022.

ADDRESSES: You may submit comments by any of the following methods; however, the NRC encourages electronic comment submission through the Federal rulemaking website:

- *Federal Rulemaking Website:* Go to <https://www.regulations.gov> and search for Docket ID NRC-2022-0195. Address questions about Docket IDs in *Regulations.gov* to Stacy Schumann;

telephone: 301-415-0624; email: Stacy.Schumann@nrc.gov. For technical questions contact the individual listed in the **FOR FURTHER INFORMATION CONTACT** section of this document.

- *Email comments to:*

Hearing.Docket@nrc.gov. If you do not receive an automatic email reply confirming receipt, then contact us at 301-415-1677.

- *Fax comments to:* Secretary, U.S. Nuclear Regulatory Commission at 301-415-1101.

- *Mail comments to:* Secretary, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001, ATTN: Rulemakings and Adjudications Staff.

For additional direction on obtaining information and submitting comments, see "Obtaining Information and Submitting Comments" in the **SUPPLEMENTARY INFORMATION** section of this document.

FOR FURTHER INFORMATION CONTACT:

Stephen C. Baker, Office of International Programs, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001; telephone: 301-287-9059, email: Stephen.Baker@nrc.gov.

SUPPLEMENTARY INFORMATION:

I. Obtaining Information and Submitting Comments

A. Obtaining Information

Please refer to NRC-2022-0195 or Docket No. 11006380 when contacting the NRC about the availability of information for this action. You may obtain publicly available information related to this action the following methods:

- *Federal Rulemaking Website:* Go to <https://www.regulations.gov> and search for Docket ID NRC-2022-0195.

- *NRC's Agencywide Documents Access and Management System (ADAMS):* You may obtain publicly available documents online in the ADAMS Public Documents collection at <https://www.nrc.gov/reading-rm/adams.html>. To begin the search, select "Begin Web-based ADAMS Search." For problems with ADAMS, please contact the NRC's Public Document Room (PDR) reference staff at 1-800-397-4209, 301-415-4737, or by email to PDR.Resource@nrc.gov. The export license application is available in ADAMS under Accession No. ML22292A007. Additional information is available in ADAMS under XW027 and Docket No. 11006380.

- *NRC's PDR:* You may examine and purchase copies of public documents, by appointment, at the NRC's PDR, Room P1 B35, One White Flint North, 11555 Rockville Pike, Rockville, Maryland 20852. To make an

appointment to visit the PDR, please send an email to PDR.Resource@nrc.gov or call 1-800-397-4209 or 301-415-4737, between 8:00 a.m. and 4:00 p.m. Eastern Time (ET), Monday through Friday, except Federal holidays.

B. Submitting Comments

The NRC encourages electronic comment submission through the Federal rulemaking website (<https://www.regulations.gov>). Please include NRC-2022-0195 or Docket No. 11006380 in your comment submission.

The NRC cautions you not to include identifying or contact information that you do not want to be publicly disclosed in your comment submission. The NRC will post all comment submissions at <https://www.regulations.gov> as well as enter the comment submissions into ADAMS. The NRC does not routinely edit comment submissions to remove identifying or contact information.

If you are requesting or aggregating comments from other persons for submission to the NRC, then you should inform those persons not to include identifying or contact information that they do not want to be publicly disclosed in their comment submission. Your request should state that the NRC does not routinely edit comment submissions to remove such information before making the comment submissions available to the public or entering the comment into ADAMS.

II. Discussion

On October 17, 2022, the NRC received an application from PFWN requesting to amend their specific license to export German-origin radioactive waste from PFWN processing facilities to Eckert and Ziegler Nuclitech GmbH located in Germany. The application seeks authorization to export no greater than 800,000 kilograms (8.5 terabecquerels (TBq)) of treated low-level radioactive waste, originally received from Germany in the form of liquid, shredded and combustible material produced from research, medical, and other industries (excluding nuclear power plants). The material to be treated includes plastics, paper, wood, personal protective equipment, and glass, primarily contaminated with carbon-14, cesium-137, cobalt-60, nickel-63, radium-226 and strontium-90. The treated waste to be returned to Germany will consist of residual ash and residual metal or non-combustible material that cannot be recycled. The applicant requests an expiration date of September 1, 2026.

In accordance with section 110.70 paragraph (b) of title 10 of the *Code of*

Federal Regulations (10 CFR) the NRC is providing notice of the receipt of the application; providing the opportunity to submit written comments concerning the application; and providing the opportunity to request a hearing or petition for leave to intervene, for a period of 30 days after publication of this notice in the **Federal Register**.

A hearing request or petition for leave to intervene must include the information specified in 10 CFR 110.82(b). Any request for hearing or petition for leave to intervene shall be served by the requestor or petitioner in accordance with 10 CFR 110.89(a), either by delivery, by mail, or filed with the NRC electronically in accordance

with the NRC's E-Filing rule (72 FR 49139; August 28, 2007, as amended at 77 FR 46562; August 3, 2012). Detailed guidance on making electronic submissions may be found in the Guidance for Electronic Submissions to the NRC and on the NRC website at <https://www.nrc.gov/site-help/e-submittals.html>.

To comply with the procedural requirements of E-Filing, at least 10 days prior to the filing deadline, the participant should contact the Office of the Secretary by email at Hearing.Docket@nrc.gov, or by telephone at 301-415-1677, to (1) request a digital identification (ID) certificate, which allows the participant

(or its counsel or representative) to digitally sign submissions and access the E-Filing system for any proceeding in which it is participating; and (2) advise the Secretary that the participant will be submitting a petition or other adjudicatory document (even in instances in which the participant, or its counsel or representative, already holds an NRC-issued digital ID certificate). Based upon this information, the Secretary will establish an electronic docket for the hearing in this proceeding if the Secretary has not already established an electronic docket.

The information concerning this application for an export license follows:

NRC EXPORT LICENSE APPLICATION

Application Information

Name of Applicant.	Perma-Fix Northwest Richland, Inc. (PFNW).
Date of Application.	October 12, 2022.
Date Received	October 17, 2022.
Application No	XW027/01.
Docket No	11006380.
ADAMS Accession No.	ML22292A007.

Description of Material

Material Type	The incoming material from Germany consists of liquid, shredded and combustible material produced from research, medical, and other industries (excluding nuclear power plants). After treatment by PFNW, radioactive waste returned to Germany will consist of residual ash and residual metal or non-combustible material that cannot be recycled. Radionuclides in the waste include carbon-14, cesium-137, cobalt-60, nickel-63, radium-226, and strontium-90.
Total Quantity	Authorization to export a total maximum quantity of waste will not exceed 800,000 kilograms. The maximum activity returned to the originating Eckert and Ziegler Nuclitech GmbH facility will not exceed 8.5 TBq.
End Use	Disposal in Germany.
Country of Destination.	Germany.

Dated: November 17, 2022.

For the Nuclear Regulatory Commission.

Peter J. Habighorst,

Acting Deputy Director, Office of International Programs.

[FR Doc. 2022-25376 Filed 11-21-22; 8:45 am]

BILLING CODE 7590-01-P

NUCLEAR REGULATORY COMMISSION

Advisory Committee on the Medical Uses of Isotopes: Call for Nominations

AGENCY: U.S. Nuclear Regulatory Commission.

ACTION: Call for Nominations.

SUMMARY: The U.S. Nuclear Regulatory Commission (NRC) is soliciting nominations for the position of Radiation Oncologist Physician (Brachytherapy) on the Advisory Committee on the Medical Uses of Isotopes (ACMUI). Nominees should be currently practicing radiation oncologists.

DATES: Nominations are due on or before January 23, 2023.

Nomination Process: Submit an electronic copy of resume or curriculum vitae, along with a cover letter, to Dr. Celimar Valentin-Rodriguez, celimar.valentin-rodriguez@nrc.gov. The cover letter should describe the nominee's current duties and

responsibilities and express the nominee's interest in the position. Please ensure that the resume or curriculum vitae includes the following information, if applicable: education; certification(s); professional association and committee membership activities; duties and responsibilities in current and previous clinical, research, and/or academic position(s).

FOR FURTHER INFORMATION CONTACT: Dr. Celimar Valentin-Rodriguez, U.S. Nuclear Regulatory Commission, Office of Nuclear Material Safety and Safeguards; (301) 415-7124; celimar.valentin-rodriguez@nrc.gov.

SUPPLEMENTARY INFORMATION: ACMUI members possess the medical and technical skills needed to address evolving issues. The current membership is comprised of the following professionals: (a) nuclear medicine physician; (b) nuclear cardiologist; (c) two radiation oncologists; (d) diagnostic radiologist; (e) therapy medical physicist; (f) nuclear medicine physicist; (g) nuclear pharmacist; (h) health care administrator; (i) radiation safety officer; (j) patients' rights advocate; (k) Food and Drug Administration representative; and (l) Agreement State representative. For additional information about membership on the ACMUI, visit the ACMUI Membership web page, <http://www.nrc.gov/about-nrc/regulatory/advisory/acmui/membership.html>.

The ACMUI brachytherapy radiation oncologist provides advice on issues associated with radiation oncology and the clinical use of brachytherapy, including the use of permanently implanted microspheres. This advice includes providing input on NRC proposed rules and guidance, providing recommendations on the training and experience requirements for physicians specializing in this use, identifying medical events associated with this use, evaluating non-routine uses of byproduct material and emerging medical technologies, bringing key issues in the radiation oncology community to the attention of NRC staff, and other radiation oncology issues as they relate to radiation safety and NRC medical use policy.

The ACMUI advises the NRC on policy and technical issues that arise in the regulation of the medical use of byproduct material. Responsibilities of an ACMUI member include providing comments on changes to the NRC regulations and guidance; evaluating certain non-routine uses of byproduct material; providing technical assistance in licensing, inspection, and enforcement cases; and bringing key issues to the attention of the NRC staff, for appropriate action. Committee members currently serve a four-year term and may be considered for reappointment to an additional term.

Nominees must be U.S. citizens and be able to devote approximately 160 hours per year to ACMUI business. Members are expected to attend semi-annual meetings at NRC headquarters in Rockville, Maryland and to participate in teleconferences or virtual meetings, as needed. Members who are not Federal employees at the time of their appointment are compensated for their service. In addition, members are reimbursed for travel (including per

diem in lieu of subsistence) and are reimbursed secretarial and correspondence expenses. Full-time Federal employees are reimbursed for travel expenses only.

Security Background CHECK: The selected nominee will undergo a thorough security background check. Security paperwork may take the nominee several weeks to complete. Nominees will also be required to complete a financial disclosure statement to avoid conflicts of interest.

Dated at Rockville, Maryland, this 17th day of November, 2022.

For the U.S. Nuclear Regulatory Commission.

Brooke P. Clark,

Secretary of the Commission.

[FR Doc. 2022-25403 Filed 11-21-22; 8:45 am]

BILLING CODE 7590-01-P

POSTAL REGULATORY COMMISSION

[Docket Nos. MC2023-47 and CP2023-45]

New Postal Products

AGENCY: Postal Regulatory Commission.

ACTION: Notice.

SUMMARY: The Commission is noticing a recent Postal Service filing for the Commission's consideration concerning a negotiated service agreement. This notice informs the public of the filing, invites public comment, and takes other administrative steps.

DATES: *Comments are due:* November 23, 2022.

ADDRESSES: Submit comments electronically via the Commission's Filing Online system at <http://www.prc.gov>. Those who cannot submit comments electronically should contact the person identified in the **FOR FURTHER INFORMATION CONTACT** section by telephone for advice on filing alternatives.

FOR FURTHER INFORMATION CONTACT: David A. Trissell, General Counsel, at 202-789-6820.

SUPPLEMENTARY INFORMATION:

Table of Contents

- I. Introduction
- II. Docketed Proceeding(s)

I. Introduction

The Commission gives notice that the Postal Service filed request(s) for the Commission to consider matters related to negotiated service agreement(s). The request(s) may propose the addition or removal of a negotiated service agreement from the Market Dominant or the Competitive product list, or the

modification of an existing product currently appearing on the Market Dominant or the Competitive product list.

Section II identifies the docket number(s) associated with each Postal Service request, the title of each Postal Service request, the request's acceptance date, and the authority cited by the Postal Service for each request. For each request, the Commission appoints an officer of the Commission to represent the interests of the general public in the proceeding, pursuant to 39 U.S.C. 505 (Public Representative). Section II also establishes comment deadline(s) pertaining to each request.

The public portions of the Postal Service's request(s) can be accessed via the Commission's website (<http://www.prc.gov>). Non-public portions of the Postal Service's request(s), if any, can be accessed through compliance with the requirements of 39 CFR 3011.301.¹

The Commission invites comments on whether the Postal Service's request(s) in the captioned docket(s) are consistent with the policies of title 39. For request(s) that the Postal Service states concern Market Dominant product(s), applicable statutory and regulatory requirements include 39 U.S.C. 3622, 39 U.S.C. 3642, 39 CFR part 3030, and 39 CFR part 3040, subpart B. For request(s) that the Postal Service states concern Competitive product(s), applicable statutory and regulatory requirements include 39 U.S.C. 3632, 39 U.S.C. 3633, 39 U.S.C. 3642, 39 CFR part 3035, and 39 CFR part 3040, subpart B. Comment deadline(s) for each request appear in section II.

II. Docketed Proceeding(s)

1. *Docket No(s):* MC2023-47 and CP2023-45; *Filing Title:* USPS Request to Add Priority Mail, First-Class Package Service & Parcel Select Contract 4 to Competitive Product List and Notice of Filing Materials Under Seal; *Filing Acceptance Date:* November 15, 2022; *Filing Authority:* 39 U.S.C. 3642, 39 CFR 3040.130 through 3040.135, and 39 CFR 3035.105; *Public Representative:* Christopher C. Mohr; *Comments Due:* November 23, 2022.

This Notice will be published in the **Federal Register**.

Erica A. Barker,

Secretary.

[FR Doc. 2022-25335 Filed 11-21-22; 8:45 am]

BILLING CODE 7710-FW-P

¹ See Docket No. RM2018-3, Order Adopting Final Rules Relating to Non-Public Information, June 27, 2018, Attachment A at 19-22 (Order No. 4679).

POSTAL REGULATORY COMMISSION

[Docket Nos. MC2023–48 and CP2023–46;
MC2023–49 and CP2023–47]

New Postal Products

AGENCY: Postal Regulatory Commission.
ACTION: Notice.

SUMMARY: The Commission is noticing a recent Postal Service filing for the Commission's consideration concerning a negotiated service agreement. This notice informs the public of the filing, invites public comment, and takes other administrative steps.

DATES: *Comments are due:* November 28, 2022.

ADDRESSES: Submit comments electronically via the Commission's Filing Online system at <http://www.prc.gov>. Those who cannot submit comments electronically should contact the person identified in the **FOR FURTHER INFORMATION CONTACT** section by telephone for advice on filing alternatives.

FOR FURTHER INFORMATION CONTACT: David A. Trissell, General Counsel, at 202–789–6820.

SUPPLEMENTARY INFORMATION:**Table of Contents**

- I. Introduction
- II. Docketed Proceeding(s)

I. Introduction

The Commission gives notice that the Postal Service filed request(s) for the Commission to consider matters related to negotiated service agreement(s). The request(s) may propose the addition or removal of a negotiated service agreement from the Market Dominant or the Competitive product list, or the modification of an existing product currently appearing on the Market Dominant or the Competitive product list.

Section II identifies the docket number(s) associated with each Postal Service request, the title of each Postal Service request, the request's acceptance date, and the authority cited by the Postal Service for each request. For each request, the Commission appoints an officer of the Commission to represent the interests of the general public in the proceeding, pursuant to 39 U.S.C. 505 (Public Representative). Section II also establishes comment deadline(s) pertaining to each request.

The public portions of the Postal Service's request(s) can be accessed via the Commission's website (<http://www.prc.gov>). Non-public portions of the Postal Service's request(s), if any, can be accessed through compliance

with the requirements of 39 CFR 3011.301.¹

The Commission invites comments on whether the Postal Service's request(s) in the captioned docket(s) are consistent with the policies of title 39. For request(s) that the Postal Service states concern Market Dominant product(s), applicable statutory and regulatory requirements include 39 U.S.C. 3622, 39 U.S.C. 3642, 39 CFR part 3030, and 39 CFR part 3040, subpart B. For request(s) that the Postal Service states concern Competitive product(s), applicable statutory and regulatory requirements include 39 U.S.C. 3632, 39 U.S.C. 3633, 39 U.S.C. 3642, 39 CFR part 3035, and 39 CFR part 3040, subpart B. Comment deadline(s) for each request appear in section II.

II. Docketed Proceeding(s)

1. *Docket No(s):* MC2023–48 and CP2023–46; *Filing Title:* USPS Request to Add Priority Mail Contract 766 to Competitive Product List and Notice of Filing Materials Under Seal; *Filing Acceptance Date:* November 16, 2022; *Filing Authority:* 39 U.S.C. 3642, 39 CFR 3040.130 through 3040.135, and 39 CFR 3035.105; *Public Representative:* Jethro Dely; *Comments Due:* November 28, 2022.

2. *Docket No(s):* MC2023–49 and CP2023–47; *Filing Title:* USPS Request to Add Priority Mail Express, Priority Mail, First-Class Package Service & Parcel Select Contract 85 to Competitive Product List and Notice of Filing Materials Under Seal; *Filing Acceptance Date:* November 16, 2022; *Filing Authority:* 39 U.S.C. 3642, 39 CFR 3040.130 through 3040.135, and 39 CFR 3035.105; *Public Representative:* Christopher C. Mohr; *Comments Due:* November 28, 2022.

This Notice will be published in the **Federal Register**.

Erica A. Barker,
Secretary.

[FR Doc. 2022–25445 Filed 11–21–22; 8:45 am]

BILLING CODE 7710–FW–P

POSTAL SERVICE**Addition of USPS Connect™ Local Mail**

AGENCY: Postal Service™.
ACTION: Notice.

SUMMARY:

The Postal Service hereby provides notice it has filed a request with the

¹ See Docket No. RM2018–3, Order Adopting Final Rules Relating to Non-Public Information, June 27, 2018, Attachment A at 19–22 (Order No. 4679).

Postal Regulatory Commission to add USPS Connect Local Mail to the market dominant product list as a permanent price category.

DATES: The request was submitted to the Postal Regulatory Commission on November 9, 2022.

FOR FURTHER INFORMATION CONTACT:

Krista Becker at (202) 268–7345 or Nickolas Card at (202) 268–7574.

SUPPLEMENTARY INFORMATION: On November 9, 2022, the United States Postal Service filed with the Postal Regulatory Commission a *United States Postal Service Revised Request to Convert USPS Connect Local Mail to a Permanent Offering* pursuant to 39 U.S.C. 3642. Documents pertinent to this request are available at <http://www.prc.gov>, Docket No. MC2023–12.

Sarah Sullivan,

Attorney, Ethics & Legal Compliance.

[FR Doc. 2022–25363 Filed 11–21–22; 8:45 am]

BILLING CODE 7710–12–P

OFFICE OF SCIENCE AND TECHNOLOGY POLICY**Request for Information; Sustainability of Microgravity R&D During and Beyond ISS Transition**

AGENCY: Office of Science and Technology Policy (OSTP).

ACTION: Notice of request for information (RFI); correction.

SUMMARY: The White House Office of Science and Technology Policy (OSTP) published a document in the **Federal Register** on November 17, 2022, concerning a request for information to help inform the development of a National Strategy for Microgravity Research and Development (R&D). The document contained an incorrect date for the submission deadline.

FOR FURTHER INFORMATION CONTACT: Ezinne Uzo-Okoro; 202–456–4444.

SUPPLEMENTARY INFORMATION:**Correction**

In the **Federal Register** of November 17, 2022, in 87 FR 69059, correct the “Dates” caption to read:

DATES: Interested persons and organizations are invited to submit comments on or before 5:00 p.m. ET, December 31, 2022 to be considered.

Dated: November 17, 2022.

Rachel Wallace,

Deputy General Counsel.

[FR Doc. 2022–25438 Filed 11–21–22; 8:45 am]

BILLING CODE 3270–F1–P

OFFICE OF SCIENCE AND TECHNOLOGY POLICY

Request for Information; Clinical Research Infrastructure and Emergency Clinical Trials

AGENCY: White House Office of Science and Technology Policy.

ACTION: Request for information (RFI) on clinical research infrastructure and emergency clinical trials; extension of comment period.

SUMMARY: On October 26, 2022, the Office of Science and Technology Policy (OSTP) published in the **Federal Register** a document entitled “Request for Information (RFI) on Clinical Research Infrastructure and Emergency Clinical Trials.” This RFI invited comments on improving the U.S. clinical trials infrastructure and in particular, our ability to carry out emergency clinical trials. In accordance with the 2022 National Biodefense Strategy for Countering Biological Threats, Enhancing Pandemic Preparedness, and Achieving Global Health Security (National Biodefense Strategy) and the American Pandemic Preparedness Plan (AP3), OSTP, in partnership with the National Security Council (NSC), is leading efforts to ensure that coordinated and large-scale clinical trials can be efficiently carried out across a range of institutions and sites to address outbreaks of disease and other emergencies. In response to requests by prospective commenters that they would benefit from additional time to adequately consider and respond to the RFI, OSTP has determined that an extension of the comment period until January 27, 2023 is appropriate.

DATES: The end of the comment period for the document entitled “Request for Information (RFI) on Clinical Research Infrastructure and Emergency Clinical Trials,” published on October 26, 2022 (87 FR 64821), is extended from December 27, 2022 to January 27, 2023.

ADDRESSES: Comments submitted in response to 87 FR 64821 should be submitted electronically to emergencyclinicaltrials@ostp.eop.gov and should include “Emergency Clinical Trials RFI” in the subject line of the email. Due to time constraints, mailed paper submissions will not be accepted, and electronic submissions received after the deadline cannot be ensured to be incorporated or taken into consideration.

Instructions: Response to this RFI (87 FR 64821) is voluntary. Each responding entity (individual or organization) is requested to submit only one response.

Please feel free to respond to one or as many prompts as you choose. Please be concise with your submissions, which must not exceed 8 pages in 12-point or larger font, with a page number on each page. Responses should include the name of the person(s) or organization(s) filing the comment.

OSTP invites input from all stakeholders, including members of the public, representing all backgrounds and perspectives. In particular, OSTP is interested in input from research institutions, clinical trialists, health care providers interested in clinical research, contract research organizations (CROs) and other clinical trial service providers, pharmaceutical and biotechnology companies, and community health care organizations. *Please indicate which of these stakeholder types, or what other description, best fits you as a respondent.* If a comment is submitted on behalf of an organization, the individual respondent’s role in the organization may also be provided on a voluntary basis.

Comments containing references, studies, research, and other empirical data that are not widely published should include copies or electronic links of the referenced materials. No business proprietary information, copyrighted information, or personally identifiable information should be submitted in response to this RFI (87 FR 64821). Please be aware that comments submitted in response to this RFI (87 FR 64821) may be posted on OSTP’s website or otherwise released publicly.

In accordance with FAR 15.202(3), responses to this notice are not offers and cannot be accepted by the Federal Government to form a binding contract. Additionally, those submitting responses are solely responsible for all expenses associated with response preparation.

FOR FURTHER INFORMATION CONTACT: For additional information, please direct questions to Grail Sipes at 202-456-4444 or emergencyclinicaltrials@ostp.eop.gov.

SUPPLEMENTARY INFORMATION: In accordance with the 2022 National Biodefense Strategy and the American Pandemic Preparedness Plan (AP3), OSTP, in partnership with NSC, is leading efforts to ensure that coordinated and large-scale clinical trials can be efficiently carried out across a range of institutions and sites to address outbreaks of disease and other emergencies. On October 26, 2022, OSTP published in the **Federal Register** a document inviting comments on improving the U.S. clinical trials

infrastructure and in particular, our ability to carry out emergency clinical trials (87 FR 64821). The RFI was issued to seek input from a broad array of stakeholders on topics including the potential establishment of a U.S.-level governance structure; outreach to a wide range of institutions, clinical trial networks, and other potential trial sites that can participate in emergency research, both domestically and internationally; and ways to expand clinical research into underserved communities, as well as increase diversity among both trial participants and clinical trial investigators. The document stated that the comment period would close on December 27, 2022. OSTP has received requests to extend the comment period. An extension of the comment period will provide additional opportunity for the public to consider the RFI and prepare comments to address the topics listed therein. Therefore, OSTP is extending the end of the comment period for the RFI from December 27, 2022 to January 27, 2023.

Submitted by the White House Office of Science and Technology Policy on November 15, 2022.

Stacy Murphy,
Operations Manager.

[FR Doc. 2022–25163 Filed 11–21–22; 8:45 am]

BILLING CODE 3270-F9-P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–96334; File No. SR–PEARL–2022–48]

Self-Regulatory Organizations; MIAx PEARL, LLC; Notice of Filing and Immediate Effectiveness of a Proposed Rule Change To Amend Rule 2614(f), Self-Trade Protection Modifiers

November 16, 2022.

Pursuant to the provisions of Section 19(b)(1) of the Securities Exchange Act of 1934 (“Act”) ¹ and Rule 19b–4 thereunder, ² notice is hereby given that on November 7, 2022, MIAx PEARL, LLC (“MIAx Pearl” or the “Exchange”) filed with the Securities and Exchange Commission (“Commission”) a proposed rule change as described in Items I and II below, which Items have been prepared by the Exchange. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

¹ 15 U.S.C. 78s(b)(1).

² 17 CFR 240.19b–4.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange is filing a proposed rule change expand the availability of the Exchange's existing Self-Trade Protection ("STP") modifiers to more Equity Members³ on the Exchange's equity trading platform (referred to herein as "MIAX Pearl Equities").

The text of the proposed rule change is available on the Exchange's website at <http://www.miaxoptions.com/rule-filings/pearl> at MIAX Pearl's principal office, and at the Commission's Public Reference Room.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the Exchange included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant aspects of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

The Exchange proposes to amend Exchange Rule 2614(f) to expand the availability of the Exchange's existing STP modifiers to more Equity Members on MIAX Pearl Equities.⁴ Specifically, the Exchange proposes to allow Equity Members to apply STP to orders submitted by an Affiliate⁵ that is also an

Equity Member (an Equity Member Affiliate), if they choose.

The Exchange offers optional anti-internalization functionality to Users⁶ in the form of STP modifiers that enable a User to prevent two of its orders from executing against each other. Currently, Users can set the STP modifier to apply at the market participant identifier ("MPID"), Exchange Member identifier, or trading group identifier (any such existing identifier, a "Unique Identifier").⁷ The STP modifier on the order with the most recent time stamp controls the interaction between two orders marked with STP modifiers. STP functionality assists market participants in reducing trading costs from unwanted executions potentially resulting from the interaction of executable buy and sell trading interest from the same firm.

The proposed rule change would permit Equity Members to direct that orders entered into the System not execute against orders entered across MPIDs that are Equity Member Affiliates. The Exchange believes that this enhancement will provide helpful flexibility for Equity Members that wish to prevent trading against all orders entered by market participants that are affiliated with each other, instead of just orders that are entered under the same Unique Identifier (as currently defined).

The Exchange offers the following four (4) STP modifiers to Equity Members: Cancel Newest, Cancel Oldest, Decrement and Cancel, and Cancel Both. An order marked with the Cancel Newest modifier will not execute against a contra-side order marked with any STP modifier originating from the same Unique Identifier (as currently defined) and the order with the most recent time stamp marked with the Cancel Newest modifier will be cancelled. The contra-side order with the older timestamp marked with an STP modifier will remain on the MIAX Pearl Equities Book.⁸ An order marked with the Cancel Oldest modifier will not execute against a contra-side order marked with any STP modifier originating from the same Unique Identifier and the order with the older time stamp marked with the STP modifier will be cancelled. The contra-side order with the most recent timestamp marked with the STP

modifier will remain on the MIAX Pearl Equities Book. An order marked with the Decrement and Cancel modifier will not execute against contra-side interest marked with any STP modifier originating from the same Unique Identifier. If both orders are equivalent in size, both orders will be cancelled. If both orders are not equivalent in size, the equivalent size will be cancelled and the larger order will be decremented by the size of the smaller order, with the balance remaining on the MIAX Pearl Equities Book. Finally, an order marked with the Cancel Both modifier will not execute against contra-side interest marked with any STP modifier originating from the same Unique Identifier and the entire size of both orders will be cancelled.

The Exchange understands that some Equity Members would like to apply STP to orders submitted by their Affiliates who are also Equity Members. For example, if Equity Member A is under common control with Equity Member B, the two Equity Members would like the option of applying STP to orders submitted by the two Equity Member Affiliates. Therefore, the Exchange proposes to expand the availability of the anti-internalization functionality it offers by allowing STP groups to be set at the Equity Member Affiliate level in addition to the current options of settings at the MPID, Exchange Member identifier, or trading group identifier level. This proposal is designed to offer STP functionality to Equity Member Affiliates that have divided their business activities between separate corporate entities without disadvantaging them when compared to Equity Members that operate those business activities within a single corporate entity. This proposal would expand the levels at which STP groups can be set by an Equity Member, but nothing in this proposal would change the manner in which two orders in the same STP group interact.

Specifically, the Exchange proposes to amend Exchange Rule 2614(f) to include "Equity Member Affiliate" as one of the possible levels for STP groupings (in addition to the current options of MPID, Exchange Member identifier, and trading group identifier). The Exchange also proposes to amend Exchange Rule 2614(f) to specify that for purposes of the rule, the term "Equity Member Affiliate" shall mean an Equity Member that is affiliated with another Equity Member pursuant to Exchange Rule 100.⁹ If Equity Members choose to have STP applied across Equity Member Affiliates, the anti-internalization

³ The term "Equity Member" is a Member authorized by the Exchange to transact business on MIAX Pearl Equities. See Exchange Rule 1901.

⁴ The Exchange notes that provisions of Exchange Rule 2614 that are not subject to this proposed rule change were amended in separate filings, but those amendments have not yet been implemented. See, e.g., Securities Exchange Act Release Nos. 95679 (September 6, 2022), 87 FR 55866 (September 12, 2022) (SR-PEARL-2022-34); and 96205 (November 1, 2022) (SR-PEARL-2022-43).

⁵ The term "affiliate" of or person "affiliated with" another person means a person who, directly, or indirectly, controls, is controlled by, or is under common control with, such other person. See Exchange Rule 100. The term "person" refers to a natural person, corporation, partnership (general or limited), limited liability company, association, joint stock company, trust, trustee of a trust fund, or any organized group of persons whether incorporated or not and a government or agency or political subdivision thereof. *Id.*

⁶ The term "User" means any Member or Sponsored Participant who is authorized to obtain access to the System pursuant to Exchange Rule 2602. See Exchange Rule 1901.

⁷ See Exchange Rule 2614(f).

⁸ Exchange Rule 1901 defines the term "MIAX Pearl Equities Book" as "the electronic book of orders in equity securities maintained by the System."

⁹ See *supra* note 5.

functionality would prevent orders from such Equity Member Affiliates from trading against one another.

Assume Equity Member A and Equity Member B satisfy the definition of Equity Member Affiliate and instructed the Exchange to prohibit their orders that contain STP modifiers from executing against one another. Under this proposal, if Equity Member A submits an order to buy 100 shares of security ABC for \$10.00 with an Equity Member-supplied STP modifier, and Equity Member B, an Equity Member Affiliate of Equity Member A, submits an order to sell 100 shares of security ABC for \$10.00 also with an Equity Member-supplied STP modifier, the two otherwise executable orders will not execute, but will instead interact based upon the Equity Member-supplied STP modifier on the newer order.

An Equity Member must inform the Exchange's Membership Department which other Equity Member(s) it is affiliated with and meet the definition of Equity Member Affiliate for purposes of using STP. Equity Members will be responsible for having proper internal documentation in their books and records substantiating that two or more Equity Members using STP are Equity Member Affiliates of one another. The Exchange notes that it already utilizes this grouping of Equity Member Affiliates in its fee schedule so as not to penalize two affiliated members when calculating rebate tiers.¹⁰ The Exchange also notes that other equity exchanges recently amended their rules to allow affiliate grouping for their own anti-internalization functionality.¹¹

This proposed rule change is designed to provide additional flexibility to Equity Members in how they implement self-trade prevention provided by the Exchange, and thereby better manage their order flow and prevent undesirable executions or the potential for "wash sales" that may occur as a result of the speed of trading in today's marketplace. Based on informal discussions with Equity Members, the Exchange believes that the proposed amendments will be useful to Equity Members in

implementing their own compliance controls. Furthermore, the additional STP functionality may assist Members in complying with certain rules and regulations of the Employee Retirement Income Security Act ("ERISA") that preclude and/or limit managing broker-dealers of such accounts from trading as principal with orders generated for those accounts.

The Exchange notes that, as with the current anti-internalization functionality offered by the Exchange, use of the proposed new Equity Member Affiliate STP grouping will not alleviate, or otherwise exempt, Equity Members from their best execution obligations. As such, Equity Members and their Affiliates using STP will continue to be obligated to take appropriate steps to ensure customer orders which were prevented from execution due to anti-internalization ultimately receive the same price, or a better price, than they would have received had execution of the orders not been inhibited by anti-internalization. Further, as with current rule provisions, Market Makers and other Users may not use STP functionality to evade the firm quote obligation, as specified in Exchange Rule 2606(b), and the STP functionality must be used in a manner consistent with just and equitable principles of trade.¹² For these reasons, the Exchange believes the proposed new Equity Member Affiliate level of STP grouping offers Equity Members enhanced order processing functionality that may prevent potentially undesirable executions without negatively impacting broker-dealer best execution obligations.

Implementation

Due to the technological changes associated with this proposed change, the Exchange will issue a trading alert publicly announcing the implementation date of this proposed rule change to provide Equity Members with adequate time to prepare for the associated technological changes. The Exchange anticipates that the implementation date will be in the fourth quarter of 2022.

2. Statutory Basis

The proposed rule change is consistent with Section 6(b) of the Act,¹³ in general, and furthers the objectives of Section 6(b)(5),¹⁴ in particular, because it is designed to prevent fraudulent and manipulative acts and practices, to promote just and

equitable principles of trade, to foster cooperation and coordination with persons engaged in regulating, clearing, settling, processing information with respect to, and facilitating transactions in securities, to remove impediments to and perfect the mechanism of a free and open market and a national market system, and, in general, to protect investors and the public interest. Specifically, the Exchange believes that the proposed rule change is consistent with the protection of investors and the public interest because allowing Equity Member Affiliates to be part of the same STP group will provide Equity Members with additional flexibility with respect to how they implement self-trade protections provided by the Exchange that may better support their trading strategies and compliance controls. Equity Members that prefer the current anti-internalization groupings offered by the Exchange can continue to use them without any modification (*i.e.*, if two Equity Member Affiliates do not wish to have orders from the two Equity Members be in the same STP group, the Equity Members will not have to make any changes to the manner in which they submit orders to the Exchange).

As noted in the Purpose section, the Exchange believes that providing Equity Members with more flexibility and control over the interactions of their orders will better prevent undesirable executions or the potential for "wash sales" that may occur as a result of the speed of trading in today's marketplace. The Equity Member Affiliate level STP grouping may better assist Equity Members in complying with certain ERISA rules and regulations that preclude and/or limit managing broker-dealers of such accounts from trading as principal with orders generated for those accounts.

Additionally, as discussed in the Purpose section, allowing Equity Members to apply STP to trades submitted by their Affiliates that are also Equity Members is intended to avoid disparate treatment of firms that have divided their various business activities between separate corporate entities as compared to firms that operate those business activities within a single corporate entity. Accordingly, the Exchange believes that this proposed rule change is fair and equitable, and not unreasonably discriminatory.

Further, the Exchange believes that providing expanded STP grouping options may streamline certain regulatory functions by reducing false positive results that may occur on wash trading surveillance reports when two orders in the same STP group are

¹⁰ See the definition of ADAV in the Exchange's fee schedule available at https://www.miaxoptions.com/sites/default/files/fee-schedule-files/MLAX_Pearl_Equities_Fee_Schedule_09012022.pdf (dated September 1, 2022).

¹¹ See, e.g., Securities Exchange Act Release Nos. 96187 (October 31, 2022), 87 FR 6674 (November 4, 2022) (SR-IEX-2022-08) (filed for immediate effectiveness on October 24, 2022); 96156 (October 25, 2022), 87 FR 65633 (October 31, 2022) (SR-BX-2022-020) (filed for immediate effectiveness on October 21, 2022); and 96154 (October 25, 2022), 87 FR 65631 (October 31, 2022) (SR-Phlx-2022-43) (filed for immediate effectiveness on October 21, 2022).

¹² See Exchange Rule 2100.

¹³ 15 U.S.C. 78f(b).

¹⁴ 15 U.S.C. 78f(b)(5).

executed, notwithstanding that the transaction may not constitute a wash trade.

Finally, as discussed in the Purpose section, the Exchange notes other equity exchanges recently amended their rules to allow affiliate grouping for their own anti-internalization functionality.¹⁵ Consequently, the Exchange does not believe that the proposed rule change raises any new or novel issues not already considered by the Commission.

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that the proposed rule change will impose any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act. To the contrary, the proposal is designed to enhance the Exchange's competitiveness by providing additional flexibility over the level at which orders are grouped, thereby incentivizing Equity Members to send orders to the Exchange and increase the liquidity available on the Exchange. Additionally, the proposed rule change is designed to assist Equity Members with compliance with the securities laws that prohibit wash trading as well as ERISA requirements. The Exchange also notes that the proposed new STP grouping option, like the Exchange's current anti-internalization functionality, is completely optional and Equity Members can determine on an order-by-order, MPID, Exchange Member identifier, trading group identifier, or Equity Member Affiliate identifier basis whether to apply anti-internalization protections to orders submitted to the Exchange. The proposed rule change would also improve the Exchange's ability to compete with other exchanges that recently amended their rules to allow affiliate grouping for their own anti-internalization functionality.¹⁶

The Exchange does not believe that the proposed rule change will impose any burden on intermarket competition that is not necessary or appropriate in furtherance of the purposes of the Act. Moreover, there is no barrier to other national securities exchanges adopting similar anti-internalization grouping at the Equity Member Affiliate level.

The Exchange also does not believe that the proposed rule change will impose any burden on intramarket competition that is not necessary or appropriate in furtherance of the purposes of the Act. All Equity Members will continue to be eligible to use the Exchange's anti-internalization

functionality. While not every Equity Member engages in a business that might involve risks of self-matching against an Affiliate's orders, for the Equity Members that do face that risk, the proposed additional anti-internalization grouping is designed to help such Equity Members with their compliance with the securities laws and ERISA. Further, implementation of anti-internalization functionality impacts only an Equity Member's orders (and the orders of the Equity Member Affiliates), and not the orders of other, unaffiliated Equity Members. As discussed in the Purpose and Statutory Basis sections, allowing Equity Members to apply STP to trades submitted by their Affiliates that are also Equity Members is intended to avoid disparate treatment of firms that have divided their various business activities between separate corporate entities as compared to firms that operate those business activities within a single corporate entity.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

No written comments were either solicited or received.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

Because the foregoing proposed rule change does not: (i) significantly affect the protection of investors or the public interest; (ii) impose any significant burden on competition; and (iii) become operative for 30 days after the date of the filing, or such shorter time as the Commission may designate if consistent with the protection of investors and the public interest, it has become effective pursuant to Section 19(b)(3)(A) of the Act¹⁷ and Rule 19b-4(f)(6)¹⁸ thereunder.

A proposed rule change filed under Rule 19b-4(f)(6)¹⁹ normally does not become operative prior to 30 days after the date of the filing. However, pursuant to Rule 19b-4(f)(6)(iii),²⁰ the Commission may designate a shorter time if such action is consistent with the protection of investors and the public

interest. The Exchange has asked the Commission to waive the 30-day operative delay so that the proposed rule change may become operative upon filing. The Exchange states that waiver of the operative delay would be consistent with the protection of investors and the public interest because it would enable the Exchange to implement the proposed rule change as soon as possible, which would allow Equity Member Affiliates to be part of the same STP group during the operative delay period and provide Equity Members with additional flexibility in the near term with respect to how they implement self-trade protections that may better support their trading strategies and compliance controls. The Exchange also states that waiver of the operative delay would allow the Exchange to avoid disparate treatment during the operative delay period of firms that have divided their various business activities between separate corporate entities as compared to firms that operate those business activities within a single corporate entity. Further, other equity exchanges recently amended their rules to allow affiliate grouping for their anti-internalization functionalities. For these reasons, and because the proposed rule change does not raise any novel regulatory issues, the Commission believes that waiving the 30-day operative delay is consistent with the protection of investors and the public interest. Therefore, the Commission hereby waives the operative delay and designates the proposal operative upon filing.²¹

At any time within 60 days of the filing of the proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act. If the Commission takes such action, the Commission shall institute proceedings to determine whether the proposed rule should be approved or disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

²¹ For purposes only of waiving the 30-day operative delay, the Commission has considered the proposed rule's impact on efficiency, competition, and capital formation. See 15 U.S.C. 78c(f).

¹⁵ See *supra* note 12 [sic].

¹⁶ See *id.*

¹⁷ 15 U.S.C. 78s(b)(3)(A).

¹⁸ 17 CFR 240.19b-4(f)(6). In addition, Rule 19b-4(f)(6) requires a self-regulatory organization to give the Commission written notice of its intent to file the proposed rule change, along with a brief description and text of the proposed rule change, at least five business days prior to the date of filing of the proposed rule change, or such shorter time as designated by the Commission. The Exchange has satisfied this requirement.

¹⁹ 17 CFR 240.19b-4(f)(6).

²⁰ 17 CFR 240.19b-4(f)(6)(iii).

Electronic Comments

- Use the Commission's internet comment form (<http://www.sec.gov/rules/sro.shtml>); or
- Send an email to rule-comments@sec.gov. Please include File Number SR-PEARL-2022-48 on the subject line.

Paper Comments

- Send paper comments in triplicate to Secretary, Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549-1090.

All submissions should refer to File Number SR-PEARL-2022-48. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's internet website (<http://www.sec.gov/rules/sro.shtml>). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for website viewing and printing in the Commission's Public Reference Room, 100 F Street NE, Washington, DC 20549, on official business days between the hours of 10:00 a.m. and 3:00 p.m. Copies of the filing also will be available for inspection and copying at the principal office of the Exchange. All comments received will be posted without change. Persons submitting comments are cautioned that we do not redact or edit personal identifying information from

comment submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR-PEARL-2022-48 and should be submitted on or before December 13, 2022.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.²²

Sherry R. Haywood,

Assistant Secretary.

[FR Doc. 2022-25358 Filed 11-21-22; 8:45 am]

BILLING CODE 8011-01-P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34-96329; File No. SR-Phlx-2022-46]

Self-Regulatory Organizations; Nasdaq PHLX LLC; Notice of Filing and Immediate Effectiveness of Proposed Rule Change To Amend the Pricing Schedule at Options 7, Section 5

November 16, 2022.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 ("Act"),¹ and Rule 19b-4 thereunder,² notice is hereby given that on November 1, 2022, Nasdaq PHLX LLC ("Phlx" or "Exchange") filed with the Securities and Exchange Commission ("SEC" or "Commission") the proposed rule change as described in Items I, II, and III, below, which Items have been prepared by the Exchange. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange proposes to amend the Exchange's Pricing Schedule at Options 7, Section 5.D.

The text of the proposed rule change is available on the Exchange's website at <https://listingcenter.nasdaq.com/rulebook/phlx/rules>, at the principal office of the Exchange, and at the Commission's Public Reference Room.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the Exchange included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant aspects of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

The Exchange proposes to amend the pricing for its singly-listed U.S. dollar-settled foreign currency options ("FX options" or "FCOs")³ in Options 7, Section 5.D. Today, the Exchange assesses fees and rebates for executions that add or remove liquidity in simple and complex FX options orders. For simple FX options, Part A of Section 5.D outlines the following rebates for adding liquidity and fees for removing liquidity:

	Customer	Lead market maker	Market maker	Firm	Broker-dealer	Professional
Rebate for Adding Liquidity	\$0.00	\$0.20	\$0.20	\$0.00	\$0.00	\$0.00
Fee for Removing Liquidity	0.40	0.40	0.40	0.40	0.40	0.40

For complex FX options, Part B of Section 5.D outlines the following fees for removing liquidity:

	Customer	Lead market maker	Market maker	Firm	Broker-dealer	Professional
Fee for Adding Liquidity	\$0.40	\$0.40	\$0.40	\$0.40	\$0.40	\$0.40

²² 17 CFR 200.30-3(a)(12).

¹ 15 U.S.C. 78s(b)(1).

² 17 CFR 240.19b-4.

³ The Exchange will add the term "FCOs" in the Options 7, Section 5.D header. FCOs include XDB,

XDE, XDN, XDS, XDA, XDZ and XDC, and trade pursuant to Options 4C.

	Customer	Lead market maker	Market maker	Firm	Broker-dealer	Professional
Fee for Removing Liquidity	0.40	0.40	0.40	0.40	0.40	0.40

Simple FX options orders that are executed against the individual components of complex FX options orders are assessed the fees and paid the rebates in Part A. However, the individual components of complex FX options orders are assessed the fees in Part B. Transactions in FX options originating on the Exchange floor are subject to the fees for removing liquidity described above. However, if one side of the transaction originates on the Exchange floor and any other side of the trade was the result of an electronically submitted order or a quote, then the fees for removing liquidity apply to the transactions which originated on the Exchange floor, and the contracts that

are executed electronically are subject to the rebates and fees, as applicable, for simple and complex orders.

The fees for FX options executions in all electronic auctions including, but not limited to, the Quote Exhaust auction,⁴ the opening process and complex electronic auction, including the Complex Order Live Auction ("COLA"),⁵ are \$0.40 per contract for Customer,⁶ Professional,⁷ Firm,⁸ Broker-Dealer,⁹ Lead Market Maker¹⁰ and Market Maker.¹¹ Furthermore, PIXL¹² executions in FX options are charged as follows: \$0.20 per contract for Initiating Orders,¹³ and \$0.40 per contract for all other participants.

The Exchange now proposes to replace the pricing described above for simple and complex FCOs with a streamlined pricing schedule that would remove the maker/taker model as well as the current auction, floor/electronic, and simple/complex segmentations. As proposed, all Non-Customers¹⁴ will be assessed a uniform Options Transaction Charge of \$0.50 per contract for all transactions in FCOs while Customers will not be assessed any Options Transaction Charges. To effectuate the foregoing changes, the Exchange proposes to delete Parts A and B of Section 5.D in their entirety and replace them with the following fee schedule:

	Customer	Professional	Lead market maker and market maker	Broker-dealer	Firm
Options Transaction Charge	\$0.00	\$0.50	\$0.50	\$0.50	\$0.50

The Exchange also proposes to assess all market participants a surcharge of \$0.25 per contract for all complex orders traded in FCOs.

2. Statutory Basis

The Exchange believes that its proposal is consistent with Section 6(b) of the Act,¹⁵ in general, and furthers the objectives of Sections 6(b)(4) and 6(b)(5) of the Act,¹⁶ in particular, in that it provides for the equitable allocation of reasonable dues, fees and other charges among members and issuers and other persons using any facility, and is not

designed to permit unfair discrimination between customers, issuers, brokers, or dealers.

The Exchange believes that the proposed changes in Options 7, Section 5.D in connection with the standard options transaction fees and complex surcharges for singly-listed FCOs are reasonable, equitable, and not unfairly discriminatory because the proposed changes will streamline FCO pricing for all market participants, and will incentivize market participants to transact in more FCOs on Phlx. Specifically, the Exchange will simplify

pricing by removing the maker/taker model as well as the current auction, floor/electronic, and simple/complex segmentations. The Exchange believes that it is reasonable to eliminate the \$0.20 per contract rebate currently offered to Lead Market Makers and Market Makers for adding liquidity in simple FCOs because this incentive has not been effective at encouraging these market participants to add increased liquidity in simple FCOs. The Exchange further believes that eliminating the differentiated pricing between maker/taker, auction, floor/electronic, and

⁴ A Quote Exhaust occurs when the Exchange's disseminated market at a particular price level includes a quote, and such market is exhausted by an inbound contra-side quote or order ("initiating quote or order"), and following such exhaustion, contracts remain to be executed from the initiating quote or order through the initial execution price. See Options 3, Section 6(a)(2)(B)(2).

⁵ Complex orders on the complex order book may be subject to an automated auction process pursuant to Options 3, Section 14(e).

⁶ The term "Customer" applies to any transaction that is identified by a member or member organization for clearing in the Customer range at The Options Clearing Corporation ("OCC") which is not for the account of a broker or dealer or for the account of a "Professional" (as that term is defined in Options 1, Section 1(b)(45)).

⁷ The term "Professional" applies to transactions for the accounts of Professionals, as defined in Options 1, Section 1(b)(45) means any person or entity that (i) is not a broker or dealer in securities, and (ii) places more than 390 orders in listed options per day on average during a calendar month for its own beneficial account(s).

⁸ The term "Firm" applies to any transaction that is identified by a member or member organization for clearing in the Firm range at OCC.

⁹ The term "Broker-Dealer" applies to any transaction which is not subject to any of the other transaction fees applicable within a particular category.

¹⁰ The term "Lead Market Maker" applies to transactions for the account of a Lead Market Maker (as defined in Options 2, Section 12(a)). A Lead Market Maker is an Exchange member who is registered as an options Lead Market Maker pursuant to Options 2, Section 12(a). An options Lead Market Maker includes a Remote Lead Market Maker which is defined as an options Lead Market Maker in one or more classes that does not have a physical presence on an Exchange floor and is approved by the Exchange pursuant to Options 2, Section 11.

¹¹ The term "Market Maker" is defined in Options 1, Section 1(b)(28) as a member of the Exchange who is registered as an options Market Maker pursuant to Options 2, Section 12(a). A Market Maker includes SQTs and RSQTs as well as Floor Market Makers.

¹² PIXL is the Exchange's electronic price improvement auction. See Options 3, Section 13.

¹³ A member may electronically submit for execution an order it represents as agent on behalf of a Public Customer, broker-dealer, or any other entity ("PIXL Order") against principal interest or against any other order (except as provided in subparagraph (a)(6) of Options 3, Section 13) it represents as agent (an "Initiating Order") provided it submits the PIXL Order for electronic execution into the PIXL Auction ("Auction") pursuant to Options 3, Section 13. See Options 3, Section 13.

¹⁴ The term "Non-Customer" applies to transactions for the accounts of Lead Market Makers, Market Makers, Firms, Professionals, Broker-Dealers and JBOs. The term "Joint Back Office" or "JBO" applies to any transaction that is identified by a member or member organization for clearing in the Firm range at OCC and is identified with an origin code as a JBO. A JBO will be priced the same as a Broker-Dealer.

¹⁵ 15 U.S.C. 78f(b).

¹⁶ 15 U.S.C. 78f(b)(4) and (5).

simple/complex FCO transactions is reasonable as it will simplify the fee structure in a manner that may make the fee schedule more comprehensible and administrable and thus, more appealing to, market participants.

As proposed, all Non-Customers will instead be assessed a uniform Options Transaction Charge of \$0.50 per contract for all transactions in FCOs while Customers will not be assessed any Options Transaction Charges. While Non-Customers will be charged higher Options Transaction Fees under the proposed pricing program,¹⁷ the Exchange believes that the proposal is reasonable and would continue to incentivize these market participants to transact in singly-listed FCOs because the proposed fees generally remain lower than the fees currently charged for the Exchange's other singly-listed options.¹⁸ In addition, Customers would no longer be assessed any standard transaction charges for FCOs whereas today, they would be assessed a \$0.40 per contract fee for removing liquidity. As a result, the Exchange believes that the proposed pricing is structured in a way that continues to encourage market participants, including Customers in particular, to transact in singly-listed FCOs on Phlx.

The Exchange believes that the proposed standard Options Transaction Charges are equitable and not unfairly discriminatory because they will apply uniformly to all similarly situated market participants. With respect to the proposal to assess no Options Transaction Charges to Customers, the Exchange notes that there is a history in the options markets of providing preferential treatment to customers, and customer order flow attracts additional liquidity to the Exchange. The Exchange believes that additional Customer order flow in FCOs will provide all market participants with more trading opportunities and encourage an increase in Lead Market Maker and Market Maker activity, which facilitates tighter spreads. This may cause an additional

corresponding increase in order flow from other market participants, contributing overall towards a robust and well-balance market ecosystem, particularly in FCOs.

The Exchange believes that the proposed complex surcharge is reasonable as the surcharge is designed to update fees for Phlx's services to reflect their current value—rather than their value when the FCO pricing was adopted in its present form eight years ago¹⁹—based on Phlx's ability to deliver value to its customers by offering singly-listed products on its market like FCOs. Even with the complex surcharge, all market participants except Lead Market Makers and Market Makers would be assessed consistent or lower fees for their singly-listed FCO orders compared to the fees currently assessed to other singly-listed options orders.²⁰ Customer FCO transactions, in particular, will continue to get the benefit of lower pricing even with the complex surcharge. Customer orders bring valuable liquidity to the market, which liquidity benefits other market participants through more trading opportunities. This, in turn, attracts Lead Market Maker and Market Maker activity, which facilitates tighter spreads, which may cause an additional corresponding increase in order flow from other market participants. Further, the Exchange believes that applying the complex surcharge consistently across all market participants, in conjunction with the uniform pricing described above, will streamline the fee structure in a manner that may make the fee schedule may be more comprehensible and administrable to the benefit of all market participants. Lastly, the Exchange believes that the proposed complex surcharge is equitable and not unfairly discriminatory as the surcharge will apply uniformly to all market participants.

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that the proposed rule change will impose any burden on competition not

necessary or appropriate in furtherance of the purposes of the Act. In terms of intra-market competition, the proposed pricing for singly-listed FCOs will apply uniformly to all similarly situated market participants. Specifically, all Non-Priority Customers will be assessed a uniform Options Transaction Charge while Customers will not be assessed any Options Transaction Charges. In addition, all market participants will be assessed a uniform surcharge on their complex FCO transactions. Even with the complex surcharge, Customers will continue to be charged lower fees for FCO trades. Accordingly, the proposed FCO pricing is designed to incentivize Customer order flow in particular, which the Exchange believes will benefit all market participants by providing more trading opportunities, which attracts other market participants, thus facilitating tighter spreads and increased order flow.

In terms of inter-market competition, the Exchange notes that it operates in a highly competitive market in which market participants can readily favor competing venues if they deem fee levels at a particular venue to be excessive, or rebate opportunities available at other venues to be more favorable. In such an environment, the Exchange must continually adjust its fees to remain competitive with other exchanges and with alternative trading systems that have been exempted from compliance with the statutory standards applicable to exchanges. Because competitors are free to modify their own fees in response, and because market participants may readily adjust their order routing practices, the Exchange believes that the degree to which fee changes in this market may impose any burden on competition is extremely limited. In sum, if the changes proposed herein are unattractive to market participants, it is likely that the Exchange will lose market share as a result. Accordingly, the Exchange does not believe that the proposed changes will impair the ability of members or competing order execution venues to maintain their competitive standing in the financial markets.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

No written comments were either solicited or received.

¹⁷ As discussed above, Non-Customers are currently charged a \$0.40 per contract fee for removing liquidity in simple and complex FCOs. For simple FCOs, Firms, Broker-Dealers, and Professionals have the opportunity to receive free executions for adding liquidity in FCOs, while Lead Market Makers and Market Makers may receive a \$0.20 per contract rebate for adding liquidity. See Options 7, Section 5.D.

¹⁸ As set forth in Options 7, Section 5.C, the Exchange currently charges Firms, Broker-Dealers, and Professionals an Options Transaction Charge of \$0.75 per contract in singly-listed options. Lead Market Makers and Market Makers are currently charged \$0.40 per contract. Lastly, Customers are charged \$0.40 per contract for transactions in singly-listed options.

¹⁹ The Exchange has not amended pricing for FCOs since 2014. See Securities Exchange Act Release No. 72806 (August 11, 2014), 79 FR 48269 (August 15, 2014) (SR-Phlx-2014-51).

²⁰ Aggregating the proposed complex surcharge and options transaction charges, all Non-Customers would be assessed \$0.75 per contract for complex trades in singly-listed FCOs while Customers would be assessed \$0.25 per contract. In contrast, under the singly-listed options pricing schedule in Options 7, Section 5.C, Firms, Broker-Dealers, and Professionals would be assessed \$0.75 per contract, and Lead Market Makers, Market Makers, and Customers would be charged \$0.40 per contract.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

The foregoing rule change has become effective pursuant to Section 19(b)(3)(A)(ii) of the Act.²¹

At any time within 60 days of the filing of the proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is: (i) necessary or appropriate in the public interest; (ii) for the protection of investors; or (iii) otherwise in furtherance of the purposes of the Act. If the Commission takes such action, the Commission shall institute proceedings to determine whether the proposed rule should be approved or disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's internet comment form (<http://www.sec.gov/rules/sro.shtml>); or send an email to rule-comments@sec.gov. Please include File Number SR-Phlx-2022-46 on the subject line.

Paper Comments

- Send paper comments in triplicate to Secretary, Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549-1090.

All submissions should refer to File Number SR-Phlx-2022-46. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's internet website (<http://www.sec.gov/rules/sro.shtml>).

Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for website viewing and printing in the Commission's Public Reference Room, 100 F Street NE,

Washington, DC 20549, on official business days between the hours of 10:00 a.m. and 3:00 p.m. Copies of the filing also will be available for inspection and copying at the principal office of the Exchange. All comments received will be posted without change. Persons submitting comments are cautioned that we do not redact or edit personal identifying information from comment submissions. You should submit only information that you wish to make available publicly.

All submissions should refer to File Number SR-Phlx-2022-46 and should be submitted on or before December 13, 2022.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.²²

Sherry R. Haywood,

Assistant Secretary.

[FR Doc. 2022-25353 Filed 11-21-22; 8:45 am]

BILLING CODE 8011-01-P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34-96332; File No. SR-PEARL-2022-50]

Self-Regulatory Organizations; MIAx PEARL, LLC; Notice of Filing and Immediate Effectiveness of Proposed Rule Change To Amend Rule 2617 Order Execution and Routing

November 16, 2022.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (the "Act")¹ and Rule 19b-4 thereunder,² notice is hereby given that on November 7, 2022, MIAx PEARL, LLC ("MIAx Pearl" or the "Exchange") filed with the Securities and Exchange Commission ("Commission") the proposed rule change as described in Items I and II below, which Items have been prepared by the Exchange. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange is filing a proposed rule change to amend the Route to Primary Auction ("PAC") routing option under Exchange Rule 2617(b)(5)(B).

The text of the proposed rule change is available on the Exchange's website at <http://www.miaxoptions.com/rule-filings/pearl> at MIAx Pearl's principal

office, and at the Commission's Public Reference Room.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the Exchange included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant aspects of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

The purpose of the proposed rule change is to amend the PAC routing option under Exchange Rule 2617(b)(5)(B) that is available to orders in equity securities traded on the Exchange's equity trading platform (referred to herein as "MIAx Pearl Equities").³ Specifically, the Exchange proposes to amend Exchange Rule 2617(b)(5)(B)(1)(i) to harmonize the timeline by which displayed Limit Orders⁴ and Market Orders⁵ with a time-in-force of Regular Hours Only ("RHO")⁶ are routed to participate in the primary listing market's opening process with the timeline by which the Exchange currently routes displayed Limit Orders to participate in the primary listing market's closing process.

The Exchange offers its Equity Members⁷ optional routing functionality that allows them to use the Exchange to access liquidity on other trading centers. The functionality

³ The Exchange notes that provisions of Exchange Rule 2617(b)(5) that are not subject to this proposed rule change were amended in a separate filing, but those amendments have not yet been implemented. See Securities Exchange Act Release No. 95298 (July 15, 2022), 87 FR 43579 (July 21, 2022) (SR-PEARL-2022-29).

⁴ See Exchange Rule 2614(a)(1).

⁵ See Exchange Rule 2614(a)(2).

⁶ Exchange Rule 2614(b)(2) defines "Regular Hours Only" or "RHO" as "[a]n order that is designated for execution only during Regular Trading Hours, which includes the Opening Process for equity securities. An order with a time-in-force of RHO entered into the System before the opening of business on the Exchange as determined pursuant to Exchange Rule 2600 will be accepted but not eligible for execution until the start of Regular Trading Hours."

⁷ The term "Equity Member" is a Member authorized by the Exchange to transact business on MIAx Pearl Equities. See Exchange Rule 1901.

²¹ 15 U.S.C. 78s(b)(3)(A)(ii).

²² 17 CFR 200.30-3(a)(12).

¹ 15 U.S.C. 78s(b)(1).

² 17 CFR 240.19b-4.

includes routing algorithms that determine the destination or pattern of routing. Exchange Rule 2617(b)(5) sets forth that there is a particular pattern of routing to other trading centers, known as the “System routing table”, as well as sets forth the Exchange’s available routing options. All routing is designed to be conducted in a manner consistent with Regulation NMS.

The Exchange recently launched the PAC routing option,⁸ which enables an Equity Member to designate that their order be routed to participate in the primary listing market’s opening, re-opening, or closing process. In sum, Exchange Rule 2617(b)(5)(B) describes PAC as a routing option for Market Orders and displayed Limit Orders designated as RHO that the entering firm wishes to designate for participation in the opening, re-opening (following a regulatory halt, suspension, or pause), or closing process of a primary listing market (Cboe BZX Exchange, Inc. (“BZX”), the New York Stock Exchange LLC (“NYSE”), The Nasdaq Stock Market LLC (“Nasdaq”), NYSE American LLC (“NYSE American”), or NYSE Arca, Inc. (“NYSE Arca”)) if received before the opening, re-opening, or closing process of such market.

According to Exchange Rule 2617(b)(5)(B)(1)(i), the Exchange routes upon receipt displayed Limit Orders and Market Orders designated as RHO coupled with the PAC routing option to participate in the primary listing market’s opening process that are received before the security has opened on the primary listing market. Meanwhile, the Exchange handles displayed Limit Orders designated as RHO coupled with the PAC routing option that are to be routed to the primary listing market’s closing process differently. In sum, the Exchange accepts displayed Limit Orders that include a time-in-force of RHO and designated to be routed to the primary listing market’s closing process throughout the trading day⁹ and, pursuant to Exchange Rule 2617(b)(5)(B)(1)(ii)(a), routes those

orders to participate in the primary listing market’s closing process prior to the primary listing market’s order entry cut-off time. The Exchange currently routes such orders at 3:49:59 p.m. Eastern Time.¹⁰ Such orders received after 3:49:59 p.m. Eastern Time, but before the primary listing market performs its closing process are, however, routed upon receipt after first checking the System for available shares pursuant to Exchange Rule 2617(b)(5)(B)(1)(ii)(a).¹¹

The Exchange proposes to route displayed Limit Orders and Market Orders designated as RHO coupled with the PAC routing option to the primary listing market’s opening process in a similar fashion as Limit Orders that are to be routed to the primary listing market’s closing process. As it does for displayed Limit Orders routed to the primary listing market’s closing process, the Exchange proposes to route displayed Limit Orders and Market Orders designated as RHO and coupled with the PAC routing option to participate in the primary listing market’s opening process prior to the primary listing market’s order entry cut-off time. Displayed Limit Orders and Market Orders designated as RHO that are to be routed to participate in the primary listing market’s opening process may continue to be entered as early as 7:30 a.m. Eastern Time and, pursuant to this change, the Exchange would route those orders at a set time prior to the primary listing market’s order entry cut-off time. The Exchange initially intends to route orders

pursuant to the PAC routing option to participate in the primary listing market’s opening process at 8:00:00 a.m. Eastern Time.¹² Any order received at or between 7:30:00 a.m. and 8:00:00 a.m. Eastern Time would be routed to participate in the primary listing market’s opening process at 8:00:00 a.m. Eastern Time. Orders routed at 8:00:00 a.m. Eastern Time are prioritized among each other based on the time of receipt. Any orders entered after 8:00:00 a.m. Eastern Time, but before the primary listing market conducts its opening auction, would be routed upon receipt, as is the case today.

Accordingly, the Exchange proposes to amend Exchange Rule 2617(b)(5)(B)(1)(i) to provide that “[a] displayed Limit Order or Market Order designated as RHO received before the security has opened on the primary listing market will be routed to participate in the primary listing market’s opening process prior to the primary listing market’s order entry cut-off time.” Amended Exchange Rule 2617(b)(5)(B)(1)(i) would further provide that “[i]f a displayed Limit Order or Market Order designated as RHO is received at or after the time the Exchange begins to route existing orders to participate in the primary listing exchange’s opening process, but before market open, the Exchange will route such orders to participate in the primary listing market’s opening process upon receipt.” These provisions are based on Exchange Rule 2617(b)(5)(B)(1)(ii)(a), which describes the timeline by which displayed Limit Orders designated as RHO are routed to participate in the primary listing market’s closing process pursuant to the PAC routing option.¹³

Like Exchange Rule 2617(b)(5)(B)(1)(ii)(a), amended Exchange Rule 2617(b)(5)(B)(1)(i) would not provide a deadline for order entry because the Exchange will continue to route displayed Limit Orders and Market Orders designated as RHO to participate in the primary listing market’s opening process after their order entry cut-off time. This is intended to provide Equity Members with increased opportunities to participate in the primary listing

⁸ See Securities Exchange Act Release No. 94301 (February 23, 2022), 87 FR 11739 (March 2, 2022) (SR-PEARL-2022-06). See also MIAx Pearl Equities—Expansion of Functionality Through New Route to Primary Auction (PAC) Strategy—Rollout Postponed until June 27, 2022, dated June 8, 2022, available at <https://www.miaxoptions.com/alerts/2022/06/08/miax-pearl-equities-expansion-functionality-through-new-route-primary-auction-pac> (last visited June 28, 2022).

⁹ See Exchange Rule 2600(a) (providing that “[o]rders may be entered into the System from 7:30 a.m. until 4:00 p.m. Eastern Time (or such earlier time as may be designated by the Exchange on a day when MIAx Pearl Equities closes early)”).

¹⁰ See MIAx Pearl Equities Exchange Regulatory Circular 2022-09, September 28, 2022, available at https://www.miaxoptions.com/sites/default/files/circular-files/MIAx_Pearl_Equities_RC_2022-09.pdf. The Exchange publicly announces any updates to the time at which it would route Limit Orders to participate in the primary listing market’s closing process via a regulatory circular or alert. See Securities Exchange Act Release No. 94301 (February 23, 2022), 87 FR 11739, 11742, n. 20 (March 2, 2022) (SR-PEARL-2022-06).

¹¹ Today Market Orders are generally ineligible to be routed to participate in primary listing market’s closing process. At a future date, the Exchange will begin to route Market Orders designated as RHO to participate in the primary listing market’s closing process where that order is received after 3:50:00 p.m. Eastern Time and the primary listing market declared a regulatory halt. See *supra* note 3. Amended Exchange Rule 2617(b)(5)(B)(1)(ii)(b) provides that the Exchange will only route a Market Order designated as RHO to participate in the primary listing market’s closing process when that Market Order is: (i) entered at or after 3:50 p.m. Eastern Time, but before market close, (ii) the primary listing market has declared a regulatory halt; and (iii) the primary listing market is to conduct its closing process according to their applicable rules. All other Market Orders designated as RHO received at or after the time the Exchange begins to route existing orders to participate in the primary listing market’s closing process, but before market close, will be cancelled.

¹² The Exchange will publicly announce this initial time at which it would route orders to participate in the primary listing market’s opening process and any updates to that time via a regulatory circular or alert.

¹³ Unlike when routing orders pursuant to the PAC routing option to participate in the primary listing market’s closing process, the Exchange does not first check the System for available shares prior to routing orders pursuant to the PAC routing option to participate in the primary listing market’s opening process because the Exchange does not offer a pre-market trading session at this time.

market's opening process while also accounting for whether the order entry cut-off time is changed/extended or should the primary listing market continue to accept orders after their established order entry cut-off time in accordance with their rules.¹⁴ If the primary listing market rejects or cancels the order for any reason, the Exchange will pass that rejection or cancellation along to the Equity Member that entered the order. Like for the closing process, Equity Members that seek greater certainty that their orders coupled with the PAC routing option would participate in the opening process at the primary listing market may enter their orders prior to the primary listing market's order entry cut-off time.

Pursuant to Exchange Rule 2617(b)(5)(B)(1)(i)(a), any shares of a Limit Order that remain unexecuted after attempting to execute in the primary listing market's opening process will continue to be posted to the MIAx Pearl Equities Book, executed, or routed pursuant to the Price Improvement routing option.¹⁵ Because displayed Limit Orders must be designated as RHO upon entry to be routed pursuant to the PAC routing option, an Equity Member that wants any returned unexecuted quantity of such order to be immediately returned to them would continue to need to submit an instruction to cancel any unexecuted shares upon their return to the Exchange. Any shares of a Market Order that remain unexecuted after attempting to execute in the primary listing market's opening process will continue to be cancelled pursuant to Exchange Rule 2617(b)(5)(B)(1)(i)(b).

¹⁴ See, e.g., NYSE Rule 7.35A(a) (providing that "[i]t is the responsibility of each DMM to ensure that registered securities open as close to the beginning of Core Trading Hours as possible") and NYSE Rule 7.35A(a)(4)(A) (allowing for a delayed opening). See, e.g., BZX Rule 11.23(b)(1)(A) (providing for the entry of Late Limit On Open Orders between 9:28 a.m. and 9:30 a.m.). This behavior is also similar to Nasdaq's LIST routing option that will continue to route orders to participate in the primary listing market's opening process after its order entry cut-off time. See Nasdaq Rule 4758(a)(1)(A)(x) (stating that "[a] LIST order received before the security has opened on its primary listing market will be routed to the primary listing market for participation in that market's opening process. . . . If a LIST order has been designated to participate in the opening only and is entered after the security has opened, the order will nevertheless be routed to the primary listing market; based on its designation as opening only, such an order would be expected to be rejected by the destination market, and would also be cancelled by Nasdaq if returned by the destination market.").

¹⁵ See Exchange Rule 2617(b)(5)(C) for a description of the Price Improvement routing option.

Implementation

The Exchange will issue a trading alert publicly announcing the implementation date of this proposed rule change.

2. Statutory Basis

The proposed rule change is consistent with Section 6(b) of the Act,¹⁶ in general, and furthers the objectives of Section 6(b)(5),¹⁷ in particular, because it is designed to promote just and equitable principles of trade, remove impediments to and perfect the mechanism of a free and open market and a national market system, and, in general, to protect investors and the public interest. The proposed rule change would remove impediments to a free and open market and promote just and equitable principles of trade because it would provide for consistent order handling by harmonizing the timeline by which it would route orders coupled with the PAC routing option to the primary listing market's opening process with the timeline it currently routes such displayed Limit Orders to participate in the primary listing market's closing process.

This proposed change is intended to provide Equity Members with consistent treatment of their orders when being routed to participate in the primary listing market's opening or closing process. Doing so would provide Equity Members with consistent order handling in both situations and remove any potential confusion with regard to how their orders would be handled when being routed pursuant to the PAC routing option. Retaining and queuing orders received prior to the primary listing market's order entry cut off time simplifies the Exchange's order handling processes because, for example, the Exchange is able to retain those orders for a period of time and more easily process potential order modification or cancellation requests. The Exchange also notes that use of the PAC routing option remains completely voluntary and no Equity Member is required to route orders through the Exchange and may choose other methods to access liquidity on other trading centers.

The proposal would not impede the national market system because it is not designed to disrupt the ability of the primary listing market to conduct their opening processes. The proposed rule change is similar to existing routing options already provided by other

equity exchanges¹⁸ that route orders to participate in the primary listing market's opening process at varying times. The Exchange understands other exchange's similar routing options have not disrupted the primary listing market's ability to conduct their opening process. The primary listing markets are free to reject or cancel such orders should they deem them to be inconsistent with their applicable rules.

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that the proposed rule change will impose any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act. In fact, the Exchange believes this particular proposed change to the PAC routing option would have no effect on competition because it does not believe the proposed changes would impact whether Equity Members chose to use the PAC routing option. The proposal simply seeks to provide for consistent order handling by harmonizing the timeline by which it would route orders coupled with the PAC routing option to the primary listing market's opening process with the timeline it currently routes such displayed Limit Orders to participate in the primary listing market's closing process. Also, any orders entered after the time the Exchange begins to route orders to the primary listing market's opening process, but before market open, would continue to be routed upon receipt. Therefore, the Exchange believes this proposed rule change would not burden competition in any manner.

Use of the Exchange's PAC routing option is voluntary and Equity Members have numerous alternative mechanisms for order routing, the changes will not impair the ability of Equity Members to use other means to access the primary listing market's opening process. The PAC routing option, in general, improves inter-market competition because it allows the Exchange to provide another means by which market participants may route orders to participate in the primary listing market's opening, re-opening, or closing processes that the Exchange believes is similar to that currently provided by other exchanges.¹⁹

¹⁸ See BZX Rule 11.13(b)(3)(N), Cboe EDGX Exchange, Inc. ("EDGX") Rule 11.11(g)(8) and Nasdaq Rule 4758(a)(1)(A)(x).

¹⁹ See BZX Rule 11.13(b)(3)(N) (describing the ROOC routing option), EDGX Rule 11.11(g)(8) (describing the ROOC routing option), and Nasdaq Rule 4758(a)(1)(A)(x) (describing the LIST routing option). See also *supra* note 14.

¹⁶ 15 U.S.C. 78f(b).

¹⁷ 15 U.S.C. 78f(b)(5).

The Exchange also believes that the proposal will not impose any burden on intra-market competition because it would be available to all Equity Members. Any Equity Member that seeks to have their order routed to participate in the primary listing market's opening process is free to select the PAC routing option or seek to access those markets through other means.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

No written comments were either solicited or received.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

Because the foregoing proposed rule change does not: (i) significantly affect the protection of investors or the public interest; (ii) impose any significant burden on competition; and (iii) become operative for 30 days after the date of the filing, or such shorter time as the Commission may designate if consistent with the protection of investors and the public interest, it has become effective pursuant to Section 19(b)(3)(A) of the Act²⁰ and Rule 19b-4(f)(6)²¹ thereunder.

A proposed rule change filed under Rule 19b-4(f)(6)²² normally does not become operative prior to 30 days after the date of the filing. However, pursuant to Rule 19b-4(f)(6)(iii),²³ the Commission may designate a shorter time if such action is consistent with the protection of investors and the public interest. The Exchange has asked the Commission to waive the 30-day operative delay so that the proposed rule change may become operative upon filing. The Exchange states that waiver of the operative delay would be consistent with the protection of investors and the public interest because it would enable the Exchange to implement the proposed rule change as

soon as possible. The Exchange states that this would allow the Exchange to retain and queue orders received prior to the primary listing market's order entry cut off time during the operative delay period, which would simplify the Exchange's order handling processes in the near term by, for example, enabling the Exchange to retain those orders for a period of time and more easily process potential order modification or cancellation requests. The Exchange also states that waiver of the operative delay would provide Equity Members with immediate consistent treatment of the orders that are to be routed to participate in the primary listing market's opening and closing process, thereby removing the potential for investor confusion during the operative delay period. Further, the proposed functionality is similar to existing routing options already provided by other equity exchanges. For these reasons, and because the proposed rule change does not raise any novel regulatory issues, the Commission believes that waiving the 30-day operative delay is consistent with the protection of investors and the public interest. Therefore, the Commission hereby waives the operative delay and designates the proposal operative upon filing.²⁴

At any time within 60 days of the filing of the proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act. If the Commission takes such action, the Commission shall institute proceedings to determine whether the proposed rule should be approved or disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's internet comment form (<http://www.sec.gov/rules/sro.shtml>); or
- Send an email to rule-comments@sec.gov. Please include File Number SR-PEARL-2022-50 on the subject line.

Paper Comments

- Send paper comments in triplicate to Secretary, Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549-1090.

All submissions should refer to File Number SR-PEARL-2022-50. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's internet website (<http://www.sec.gov/rules/sro.shtml>). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for website viewing and printing in the Commission's Public Reference Room, 100 F Street NE, Washington, DC 20549, on official business days between the hours of 10:00 a.m. and 3:00 p.m. Copies of the filing also will be available for inspection and copying at the principal office of the Exchange. All comments received will be posted without change. Persons submitting comments are cautioned that we do not redact or edit personal identifying information from comment submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR-PEARL-2022-50 and should be submitted on or before December 13, 2022.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.²⁵

Sherry R. Haywood,

Assistant Secretary.

[FR Doc. 2022-25356 Filed 11-21-22; 8:45 am]

BILLING CODE 8011-01-P

²⁵ 17 CFR 200.30-3(a)(12).

²⁰ 15 U.S.C. 78s(b)(3)(A).

²¹ 17 CFR 240.19b-4(f)(6). In addition, Rule 19b-4(f)(6) requires a self-regulatory organization to give the Commission written notice of its intent to file the proposed rule change, along with a brief description and text of the proposed rule change, at least five business days prior to the date of filing of the proposed rule change, or such shorter time as designated by the Commission. The Exchange has satisfied this requirement.

²² 17 CFR 240.19b-4(f)(6).

²³ 17 CFR 240.19b-4(f)(6)(iii).

²⁴ For purposes only of waiving the 30-day operative delay, the Commission has considered the proposed rule's impact on efficiency, competition, and capital formation. See 15 U.S.C. 78c(f).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–96327; File No. SR–NSCC–2022–014]

Self-Regulatory Organizations; National Securities Clearing Corporation; Notice of Filing and Immediate Effectiveness of a Proposed Rule Change To Make Certain Changes To Addendum A To Adopt Fees for the AIP Document Transfer Service as Part of AIP Attachments

November 16, 2022.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (“Act”),¹ and Rule 19b–4 thereunder,² notice is hereby given that on November 14, 2022, National Securities Clearing Corporation (“NSCC”) filed with the Securities and Exchange Commission (“Commission”) the proposed rule change as described in Items I, II and III below, which Items have been prepared by the clearing agency. NSCC filed the proposed rule change pursuant to Section 19(b)(3)(A)³ of the Act and subparagraph (f)(2)⁴ of Rule 19b–4 thereunder. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Clearing Agency’s Statement of the Terms of Substance of the Proposed Rule Change

The proposed rule change of NSCC consists of modifications to Addendum A (Fee Structure) (“Addendum A”) of NSCC’s Rules & Procedures (“Rules”) to adopt fees for the AIP document transfer service (“Document Transfer”) as part of AIP Attachments set forth in the Alternative Investment Product services (“AIP”), as described in greater detail below.⁵

II. Clearing Agency’s Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the clearing agency included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The clearing agency has prepared summaries, set forth in sections A, B,

and C below, of the most significant aspects of such statements.

(A) Clearing Agency’s Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

Overview of the Proposed Rule Change

The purpose of this proposed rule change is to adopt fees for Document Transfer. Document Transfer is a result of enhancements of the AIP Attachments service. The proposed fees will be \$1 per item, per side, as discussed below, and is designed to be consistent with NSCC’s cost-based plus markup fee model.⁶

Background

AIP, which was established in 2007, is a standardized, trading and reporting platform that links the alternative investments industry to securely and efficiently exchange data and money relating to alternative investment products, including hedge funds, funds of funds, private equity, non-traded real estate investment trusts, managed futures and limited partnerships.⁷ One of the services offered within AIP is a document transmission service, referred to as AIP Attachments in the Rules, which enables AIP Members to electronically transmit imaged documents, signatures and forms relating to alternative investment products.⁸

AIP Attachments has been in the Rules since the inception of AIP but has not been used by AIP Members in production, and fees for AIP Attachments have previously not been developed or placed in the Rules. Initially, the service was marketed with the name “paper workflow” and was a basic document facility designed to automate the transmission of imaged hard-copy documents between AIP Manufacturers and AIP Distributors.⁹

Certain AIP Members did test the capability of paper workflow, but the service was not used by AIP Members in production, and fees were not developed for the service.

In 2018, NSCC enhanced AIP Attachments to, among other things, provide that documents that were transmitted pursuant to AIP Attachments would be tied to specific transactions, and the re-designed AIP Attachments was marketed as “E-Doc.” Like paper workflow, however, AIP Members tested the capability of E-Doc, but the service was not used by AIP Members in production, and fees were not developed for the service.

During the COVID–19 pandemic, new challenges were presented to AIP Members relating to the transfer of paper documents as a result of work from home requirements for employees of AIP Members and the inability of AIP Members to use certain industry services that had been used to transmit paper documents prior to the pandemic. As a result, NSCC began discussions again with AIP Members about enhancing AIP Attachments to fulfill the needs of AIP Members with respect to the transfer of documents. As a result of those discussions, NSCC enhanced AIP Attachments to, among other things, make the requirements for the use of AIP Attachments more user friendly. In addition, AIP Attachments has been enhanced to provide the ability of AIP Members to transfer documents that are tied to specific AIP transactions and to transfer standalone documents that are not tied to specific AIP transactions. NSCC would market the new enhanced AIP Attachments as “Document Transfer.”

In order to offset the costs of building the enhancements, NSCC is proposing to add fees for the service via a simple billing structure of \$1 per item, per side. NSCC believes this billing structure will align the fees with the costs of services provided by NSCC by setting the fees so that the revenue received by NSCC would be sufficient to recover the costs of building the service.

Proposed Change to Addendum A

To effectuate the proposed Document Transfer fees, Section IV.L. of Addendum A would be updated to include a new subsection 4. for fees relating to Document Transfer, which would be \$1.00 per item, per side.

Expected Member/NSCC Impact

The proposed fee changes would impact all users of the service. The fees are intended to cover the costs of developing Document Transfer in accordance with NSCC’s cost-based plus

¹ 15 U.S.C. 78s(b)(1).

² 17 CFR 240.19b–4.

³ 15 U.S.C. 78s(b)(3)(A).

⁴ 17 CFR 240.19b–4(f)(2).

⁵ Capitalized terms used herein and not otherwise defined shall have the meaning assigned to such terms in the Rules, available at http://dtcc.com/-/media/Files/Downloads/legal/rules/nscc_rules.pdf.

⁶ NSCC has in place procedures to control costs and to regularly review pricing levels against costs of operation. NSCC’s fees are cost-based plus a markup as approved by its Board of Directors. This markup is applied to recover development costs and operating expenses, and to accumulate capital sufficient to meet regulatory and economic requirements. See NSCC Disclosure Framework for Covered Clearing Agencies and Financial Market Infrastructures, available at https://www.dtcc.com/-/media/Files/Downloads/legal/policy-and-compliance/NSCC_Disclosure_Framework.pdf, at 121.

⁷ See Securities Exchange Act Release No. 57813 (May 12, 2008), 73 FR 28539 (May 16, 2008) (SR–NSCC–2007–12) (Order Granting Approval of a Proposed Rule Change To Provide a New Alternative Investments Products Service) (“Initial Filing”).

⁸ See *id.* See also Section 8 of Rule 53, *supra* note 5.

⁹ See Initial Filing, *supra* note 7.

markup fee model¹⁰ and expected client volumes based on discussions with AIP Members. Following implementation of the fees, assuming revenues and expenses remain constant,¹¹ NSCC anticipates recouping the costs of enhancing AIP Attachments for Document Transfer within approximately three years of implementing the fees and expects to have a positive operating margin with respect to Document Transfer thereafter.

Implementation Timeline

NSCC expects to implement the proposed rule changes on November 17, 2022. As proposed, a legend would be added to Addendum A stating there are changes that became effective upon filing with the Commission but have not yet been implemented. The proposed legend also would include November 17, 2022 as the date on which such changes would be implemented and the file number of this proposal, and state that, once this proposal is implemented, the legend would be automatically removed from Addendum A.

2. Statutory Basis

NSCC believes the proposed rule change is consistent with the requirements of the Act, and the rules and regulations thereunder applicable to a registered clearing agency. Specifically, NSCC believes the proposed rule change is consistent with Section 17A(b)(3)(D) of the Act¹² and Rule 17Ad-22(e)(23)(ii),¹³ as promulgated under the Act, for the reasons set forth below.

Section 17A(b)(3)(D) of the Act¹⁴ requires that the rules of a clearing agency provide for the equitable allocation of reasonable dues, fees, and other charges among its participants. NSCC believes the proposed fees would be allocated equitably among AIP Members that use Document Transfer. NSCC would apply a fee of \$1.00 per side for each item submitted. NSCC believes that the proposed fee changes are reasonable because they were developed in consideration of the expected investment costs to develop

the Document Transfer enhancements, the projected annual costs to run the service (including both technology and non-technology run costs), and projected revenues for the service, and are expected to recover such investment and operating costs in an appropriate timeframe. NSCC notes that once the proposed Document Transfer fees are implemented, the Document Transfer fees would be periodically reviewed under NSCC's procedures to determine whether it is continuing to appropriately control its costs and to regularly review pricing levels against costs of operation.¹⁵

Rule 17Ad-22(e)(23)(ii) under the Act¹⁶ requires NSCC to establish, implement, maintain and enforce written policies and procedures reasonably designed to provide sufficient information to enable participants to identify and evaluate the risks, fees, and other material costs they incur by participating in the covered clearing agency. The proposed fees for Document Transfer would be clearly and transparently published in Addendum A of the Rules, which are available on a public website,¹⁷ thereby enabling Members to identify the fees associated with participating in the Document Transfer service. As such, NSCC believes the proposed rule change is consistent with Rule 17Ad-22(e)(23)(ii) under the Act.¹⁸

(B) Clearing Agency's Statement on Burden on Competition

NSCC does not believe the proposed rule change would impose any burden, or have any impact, on competition. The proposed fees would apply equally to all AIP Members that use Document Transfer. NSCC believes that the proposed Document Transfer fees would not advantage or disadvantage any particular member or user of Document Transfer, or unfairly inhibit access to Document Transfer. NSCC notes that members may continue to engage in document transmission outside of Document Transfer if they choose.

(C) Clearing Agency's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

NSCC has conducted outreach to AIP Members to provide them with notice of the proposed fees.

NSCC has not received or solicited any written comments relating to this proposal. If any written comments are

received by NSCC, they will be publicly filed as an Exhibit 2 to this filing, as required by Form 19b-4 and the General Instructions thereto.

Persons submitting comments are cautioned that, according to Section IV (Solicitation of Comments) of the Exhibit 1A in the General Instructions to Form 19b-4, the Commission does not edit personal identifying information from comment submissions. Commenters should submit only information that they wish to make available publicly, including their name, email address, and any other identifying information.

All prospective commenters should follow the Commission's instructions on how to submit comments, *available at* <https://www.sec.gov/regulatory-actions/how-to-submit-comments>. General questions regarding the rule filing process or logistical questions regarding this filing should be directed to the Main Office of the Commission's Division of Trading and Markets at tradingandmarkets@sec.gov or 202-551-5777.

NSCC reserves the right not to respond to any comments received.

III. Date of Effectiveness of the Proposed Rule Change, and Timing for Commission Action

The foregoing rule change has become effective pursuant to Section 19(b)(3)(A)¹⁹ of the Act and paragraph (f)²⁰ of Rule 19b-4 thereunder. At any time within 60 days of the filing of the proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's internet comment form (<http://www.sec.gov/rules/sro.shtml>); or
- Send an email to rule-comments@sec.gov. Please include File Number SR-NSCC-2022-014 on the subject line.

¹⁰ See *supra* note 6.

¹¹ It is not certain that revenues and expenses will remain constant. Costs of providing the service may change, for instance, if AIP Members request service enhancements or NSCC's technology costs change. In addition, revenues may change depending on the number of users of the service. NSCC regularly reviews pricing levels against costs of operation. As with its other services, if NSCC determines that its operating margin is too high or too low, NSCC would propose changes to pricing levels accordingly.

¹² 15 U.S.C. 78q-1(b)(3)(D).

¹³ 17 CFR 240.17Ad-22(e)(23)(ii).

¹⁴ 15 U.S.C. 78q-1(b)(3)(D).

¹⁵ See *supra* note 6.

¹⁶ 17 CFR 240.17Ad-22(e)(23)(ii).

¹⁷ See *supra* note 5.

¹⁸ 17 CFR 240.17Ad-22(e)(23)(ii).

¹⁹ 15 U.S.C. 78s(b)(3)(A).

²⁰ 17 CFR 240.19b-4(f).

Paper Comments

• Send paper comments in triplicate to Secretary, Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549.

All submissions should refer to File Number SR–NSCC–2022–014. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's internet website (<http://www.sec.gov/rules/sro.shtml>). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for website viewing and printing in the Commission's Public Reference Room, 100 F Street NE, Washington, DC 20549 on official business days between the hours of 10:00 a.m. and 3:00 p.m. Copies of the filing also will be available for inspection and copying at the principal office of NSCC and on DTCC's website (<https://dtcc.com/legal/sec-rule-filings.aspx>). All comments received will be posted without change; the Commission does not edit personal identifying information from submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR–NSCC–2022–014 and should be submitted on or before December 13, 2022.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.²¹

Sherry R. Haywood,

Assistant Secretary.

[FR Doc. 2022–25352 Filed 11–21–22; 8:45 am]

BILLING CODE 8011–01–P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–96331; File No. SR–IEX–2022–09]

Self-Regulatory Organizations; Investors Exchange LLC; Notice of Filing and Immediate Effectiveness of Proposed Rule Change Pursuant to IEX Rule 15.110 To Amend IEX's Fee Schedule

November 16, 2022.

Pursuant to section 19(b)(1)¹ of the Securities Exchange Act of 1934 (the “Act”)² and Rule 19b–4 thereunder,³ notice is hereby given that, on November 7, 2022, the Investors Exchange LLC (“IEX” or the “Exchange”) filed with the Securities and Exchange Commission (the “Commission”) the proposed rule change as described in Items I, II and III below, which Items have been prepared by the self-regulatory organization. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

Pursuant to the provisions of Section 19(b)(1) under the Act,⁴ and Rule 19b–4 thereunder,⁵ the Exchange is filing with the Commission a proposed rule change to amend the fees applicable to Members⁶ (the “Fee Schedule”), pursuant to IEX Rule 15.110(a) and (c). Changes to the Fee Schedule pursuant to this proposal are effective upon filing,⁷ and the Exchange plans to implement the changes on December 1, 2022.

The text of the proposed rule change is available at the Exchange's website at www.iextrading.com, at the principal office of the Exchange, and at the Commission's Public Reference Room.

II. Self-Regulatory Organization's Statement of the Purpose of, and the Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the self-regulatory organization included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at

the places specified in Item IV below. The self-regulatory organization has prepared summaries, set forth in Sections A, B, and C below, of the most significant aspects of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and the Statutory Basis for, the Proposed Rule Change

1. Purpose

The Exchange proposes to amend its Fee Schedule,⁸ pursuant to IEX Rule 15.110(a) and (c), to modestly increase: (i) the fees applicable to executions of and with non-displayed orders; (ii) the fees applicable to executions that remove displayed liquidity; (iii) and the fees applicable to the opening process for non-listed securities. The Exchange also proposes to reduce the fees for executions of securities priced below \$1.00 per share and to make related and conforming changes.

Non-Displayed Trading Fees

The Exchange currently charges Members a standard fee of \$0.0009 per share for non-displayed transactions, both adding and removing liquidity, with an execution price greater than or equal to \$1.00.⁹ IEX has not changed this fee for non-displayed adding and removing orders since it launched as an Exchange in 2016,¹⁰ although certain fee code combinations can result in a free execution for non-displayed adding and removing orders.¹¹

IEX recently conducted an assessment of its non-displayed adding and removing fees, including an assessment of the fees charged by its competitors, and determined that charging \$0.0009 to remove non-displayed liquidity places IEX's fee well below the most inexpensive “maker-taker”¹² venues which range from \$0.0026 to \$0.0029.¹³

⁸ See IEX Fee Schedule, available at <https://exchange.iex.io/resources/trading/fee-schedule/>.

⁹ See *supra* note 5 [sic].

¹⁰ See Securities Exchange Act Release No. 78550 (August 11, 2016), 81 FR 54873 (August 17, 2016) (SR–IEX–2016–09).

¹¹ Non-displayed Retail orders, Retail Liquidity Providing orders, and orders subject to the “Internalization Fee” (the Member executes against resting liquidity added by such Member) all execute for free. See IEX Fee Schedule.

¹² In a “maker-taker” model, an exchange will typically pay a rebate for an order that adds liquidity and charge a fee for an order that removes liquidity.

¹³ See, e.g., MIAX Pearl Equities Fee Schedule (charging a standard fee of \$0.0029 for orders that remove liquidity), https://www.miaxequities.com/sites/default/files/fee_schedule-files/MIAX_Pearl_Equities_Fee_Schedule_09012022.pdf; NYSE Fee Schedule (charging a standard fee of at least \$0.0026 for orders that remove non-displayed liquidity), https://www.nyse.com/publicdocs/nyse/markets/nyse/NYSE_Price_List.pdf

¹ 15 U.S.C. 78s(b)(1).

² 15 U.S.C. 78a.

³ 17 CFR 240.19b–4.

⁴ 15 U.S.C. 78s(b)(1).

⁵ 17 CFR 240.19b–4.

⁶ See IEX Rule 1.160(s).

⁷ 15 U.S.C. 78s(b)(3)(A)(ii).

²¹ 17 CFR 200.30–3(a)(12).

Similarly, IEX's fee for adding non-displayed liquidity places it well below the most inexpensive "taker-maker"¹⁴ venues, which range from \$0.0024 to \$0.0030.¹⁵ Additionally, IEX notes that several taker-maker exchanges also charge \$0.0010 for orders that add non-displayed midpoint liquidity.¹⁶

Therefore, IEX is proposing to modestly raise its non-displayed adding and removing fees for securities priced at or above \$1.00 from \$0.0009 to \$0.0010, with no changes to non-displayed transactions that currently execute free of charge.¹⁷ These fee increases are designed to offset increased costs to operate the Exchange. IEX notes that in the past five years, the Exchange has not adopted transaction fee changes designed to increase overall fee revenue. During that time the costs of operating the Exchange, including the costs to subscribe to other exchanges' technology products, have increased considerably.

Displayed Removing Fees

Currently, orders that add displayed liquidity to the Exchange execute free of charge, while orders that remove displayed liquidity are charged \$0.0006 (for orders priced greater than or equal to \$1.00 per share). IEX is not proposing to make any changes to the fees charged for adding displayed liquidity, but is proposing to increase the fee for removing displayed liquidity to \$0.0009.

IEX notes that its current fee for removing displayed liquidity is well below those charged by all the maker-taker exchanges (each of which charges a standard fee of \$0.0030 for removing displayed liquidity¹⁸) and is even lower than the fees charged by one "taker-maker" exchange, Nasdaq BX, which

charges a standard fee of \$0.0007 for orders that remove liquidity.¹⁹

As with the proposed changes to the non-displayed trading fees, this modest proposed fee increase is designed to offset increased costs to operate the Exchange as described above.

Opening Process Fees

IEX currently charges a fee of \$0.0009 per share for executions equal to or greater than \$1.00 per share in IEX's opening process for securities listed on other exchanges. Because this fee has been set at the same level as the non-displayed adding and removing fees, IEX is proposing to similarly increase the opening process fee to \$0.0010. This modest proposed fee increase is also designed to offset increased costs to operate the Exchange as described above.

Sub-Dollar Execution Fees

Currently, IEX charges .30% of the Total Dollar Value ("TDV") for all executions below \$1.00 per share, unless another fee code combination results in a free execution (e.g., a retail order that removes displayed liquidity). This can create a significant pricing disparity between taking orders for executions above and below \$1.00. For example, in a 1,000-share execution at \$1.01 the taker would pay a fee of \$0.60, while a 1,000-share execution at \$0.99 would pay a fee of \$2.97 or approximately five times the fee for the \$1.01 execution. IEX therefore believes it is fairer and more equitable to synchronize its sub-dollar transaction fees with its fees for executions above \$1 per share.

Thus, IEX proposes to reduce the non-displayed sub-dollar execution and opening process fees from 0.30% of TDV to 0.10% of TDV (more comparable to the new \$0.0010 fee for non-displayed executions). Similarly, as proposed, any sub-dollar executed orders that add displayed liquidity would be charged no fee, while any sub-dollar executed orders that remove displayed liquidity would be charged a fee of 0.09% of TDV.

IEX notes that its sub-dollar execution fees are currently higher than those charged by several other exchanges. For example, taker-maker exchange Cboe BYX charges 0.10% of TDV for transactions that remove liquidity,²⁰ while taker-maker exchange Cboe EDGA and maker-taker exchange NYSE both

charge no fee for sub-dollar executions that either add or remove liquidity.²¹

Conforming Changes to the Fee Schedule

As part of this fee change, IEX proposes to remove the bullet in the "Transaction Fees" section that states that "Executions below \$1.00 are assessed a fee of 0.30% of TDV unless the Fee Code Combination results in a FREE execution" and add a new column to its "Fee Code Combinations and Associated Fees" table to list the fees charged for sub-dollar executions, to reflect the proposed fee changes. In addition, IEX proposes to incorporate the existing fees for auctions in IEX listed securities into the new column.²²

2. Statutory Basis

The Exchange believes that the proposed rule change is consistent with section 6(b) of the Act,²³ in general, and furthers the objectives of section 6(b)(4)²⁴ of the Act, in particular, in that it is designed to provide for the equitable allocation of reasonable fees among IEX Members and persons using its facilities. Additionally, IEX believes that the proposed changes to the Fee Schedule are consistent with the investor protection objectives of section 6(b)(5)²⁵ of the Act, in particular, in that they are designed to prevent fraudulent and manipulative acts and practices; to promote just and equitable principles of trade; to foster cooperation and coordination with persons engaged in facilitating transactions in securities; to remove impediments to and perfect the mechanism of a free and open market and a national market system, and, in general, to protect investors and the public interest; and are not designed to permit unfair discrimination between customers, brokers, or dealers.

The Exchange believes that the proposed changes to non-displayed order executions (and opening process executions) are reasonable, fair and equitable, non-discriminatory, and consistent with the Act. The Exchange operates in a highly competitive market in which market participants can readily direct order flow to competing venues if they deem fee levels at a particular venue to be excessive. Within that context, charging \$0.0010 per share (or 0.10% of TDV for sub-dollar executions) for orders that add or remove non-displayed liquidity, as well

¹⁴ In a "taker-maker" model (also called an "inverted" exchange), an exchange will typically pay a rebate for an order that removes liquidity (or offer a free execution) and charge a fee for an order that adds liquidity.

¹⁵ See, e.g., Cboe BYX Fee Schedule (charging a standard fee of \$0.0024 to add non-displayed liquidity, https://www.cboe.com/us/equities/membership/fee_schedule/byx/; Cboe EDGA Fee Schedule (charging a standard fee of \$0.0030 to add non-displayed liquidity), https://www.cboe.com/us/equities/membership/fee_schedule/edga/.

¹⁶ This fee is charged by Cboe BYX and EDGA, see *supra* note 12 [sic], and also Nasdaq BX, http://nasdaqtrader.com/Trader.aspx?id=bx_pricing.

¹⁷ See *supra* note 8.

¹⁸ See, e.g., MIAX Pearl Equities Fee Schedule, https://www.miaxequities.com/sites/default/files/fee_schedule-files/MIAX_Pearl_Equities_Fee_Schedule_09012022.pdf; NYSE Fee Schedule, https://www.nyse.com/publicdocs/nyse/markets/nyse/NYSE_Price_List.pdf; Nasdaq Fee Schedule, <http://nasdaqtrader.com/Trader.aspx?id=PriceListTrading2>.

¹⁹ See Nasdaq BX, http://nasdaqtrader.com/Trader.aspx?id=bx_pricing.

²⁰ See Cboe BYX Fee Schedule, *supra* note 12 [sic].

²¹ See Cboe EDGA Fee Schedule, *supra* note 12 [sic]; see also NYSE Fee Schedule, *supra*, note 10 [sic].

²² There are no IEX listed securities.

²³ 15 U.S.C. 78f(b).

²⁴ 15 U.S.C. 78f(b)(4).

²⁵ 15 U.S.C. 78f(b)(5).

as opening process orders, is designed to set IEX's non-displayed pricing squarely within the fees charged by maker-taker exchanges to remove liquidity and taker-maker exchanges to add liquidity. Keeping IEX's prices competitive with those of other markets is designed to incentivize more market participants to trade on IEX and avail themselves of IEX's deep pool of non-displayed liquidity, which is consistent with the overall goal of enhancing market quality.

The Exchange also believes that the proposed changes to executions that remove displayed liquidity are reasonable, fair and equitable, non-discriminatory, and consistent with the Act. As noted above, the Exchange operates in a highly competitive market in which market participants can readily direct order flow to competing venues if they deem fee levels at a particular venue to be excessive. Within that context, charging \$0.0009 per share (or .09% of TDV for sub-dollar executions) for orders that remove displayed liquidity (coupled with continuing to offer free executions for orders that add displayed liquidity) is designed to keep IEX's displayed trading prices competitive with those of other exchanges. IEX believes that such competitive prices should incentivize Members and other market participants to enter displayed orders on IEX by providing a pricing incentive for such orders without offering rebates, thereby contributing to price discovery and price formation, which is consistent with the overall goal of enhancing market quality.

Other exchanges use "maker-taker" or "taker-maker" fee structures that apply different fees to orders that add versus remove liquidity, generally providing a rebate rather than charging a fee to adding or removing orders. In a "maker-taker" model an exchange will typically pay a rebate for an order that adds liquidity and charge a fee for an order that removes liquidity. The Exchange is not proposing to pay a rebate, but as proposed the fee to remove displayed liquidity will still be lower than the fee to add or remove non-displayed liquidity and will be within the range (and in many cases much less than) the fees charged by competing exchanges to remove displayed or non-displayed liquidity.²⁶ Consequently, IEX does not

believe that the proposed fee structure for adding or remove non-displayed liquidity, or for removing displayed liquidity, raises any new or novel issues that the Commission has not already considered in the context of other exchanges' fees. The Exchange believes that this fee structure will attract and incentivize displayed order flow as well as order flow seeking to trade with displayed order flow. Additionally, increases in displayed liquidity would contribute to the public price discovery process which would benefit all market participants and protect investors and the public interest.

The Exchange also believes that it is reasonable to decrease the fees it charges for sub-dollar executions to synchronize those fees with the fees charged for executions at or above \$1.00. These fees will result in lower transaction costs for sub-dollar executions at IEX, including for the first time allowing sub-dollar executions that add liquidity to execute free of charge.

The Exchange further believes that the proposed fee change is consistent with the Act's requirement that the Exchange provide for an equitable allocation of fees that is also not unfairly discriminatory. As proposed, the fees for adding and removing displayed and non-displayed liquidity will apply in an equal and nondiscriminatory manner to all Members. All Members are eligible to enter displayed or non-displayed orders and orders to remove displayed or non-displayed orders. Moreover, to the extent the proposed change is successful in incentivizing the entry and execution of displayed orders on IEX, such greater liquidity will benefit all market participants by increasing price discovery and price formation as well as market quality and execution opportunities.

In addition, the Exchange believes that it is reasonable to add a new column to the Fee Code Combinations and Associated Fees table to reflect the proposed fee changes and to provide information to Members on the relevant charges, including indicating how sub-dollar pricing will apply to all possible fee code combinations. This addition to the Fee Schedule will provide additional clarity for Members on transaction fees, consistent with the

objectives of section 6(b)(1)²⁷ of the Act. The revisions are designed to reflect the fee changes, and also to provide enhanced clarity to the applicable Fee Code Combinations and Associated Fees, so the Exchange does not believe that adding such information raises any new or novel issues not already considered by the Commission. Accordingly, the Exchange believes that it is reasonable to revise the Fee Code Combinations as proposed in order to reflect the applicable fees.

Further, the Exchange believes that it is reasonable to make a conforming change to delete the provision in the Fee Schedule specifying that all sub-dollar executions are assessed a fee of 0.30% of TDV unless the Fee Code Combination results in a free execution. As discussed in the Purpose section, this language is no longer accurate because sub-dollar execution fees will now be synchronized with the fees charged for executions at or above \$1.00, and deletion will avoid any unnecessary confusion as to the applicable fees.

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that the proposed rule change will impose any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act. The Exchange does not believe that the proposed fees will impose any burden on intermarket competition that is not necessary or appropriate in furtherance of the purposes of the Act. The Exchange operates in a highly competitive market in which market participants can easily direct their orders to competing venues, including off-exchange venues, if its fees are viewed as non-competitive. Moreover, IEX notes that the proposed fees are designed to enhance competition by incentivizing the entry of liquidity on IEX and thereby increasing the Exchange's pool of both displayed and non-displayed liquidity to the benefit of all market participants. Further, subject to the SEC rule filing process, other exchanges could adopt similar fees.

The Exchange also does not believe that the proposed rule change will impose any burden on intramarket competition that is not necessary or appropriate in furtherance of the purposes of the Act. While Members that remove displayed liquidity or add or remove non-displayed liquidity will be subject to different fees based on this usage, those differences are not based on the type of Member entering orders but

²⁶ See Cboe BZX Fee Schedule (charging \$0.0030 per share for any liquidity removing transactions), available at https://markets.cboe.com/us/equities/membership/fee_schedule/bzx/; MIAX Pearl Equities Free Schedule (charging \$0.0030 per share for any liquidity removing executions), available at https://www.miaxoptions.com/sites/default/files/fee_schedule-files/MIAX_PEARL_Equities_Fee_

Schedule_01292021.pdf; MEMX Fee Schedule (charging \$0.0026 per share for any liquidity removing executions), available at <https://info.memxtrading.com/fee-schedule/>; Nasdaq Equity 7 Section 118(a) (charging \$0.0030 per share for any liquidity removing executions), available at <https://listingcenter.nasdaq.com/rulebook/nasdaq/rules/nasdaq-equity-7>; NYSE Fee Schedule (charging \$0.00275 per share for any liquidity removing executions), available at <https://www.nyse.com/markets/nyse/trading-info/fees>.

²⁷ 15 U.S.C. 78f(b)(1).

on whether the Member chose to submit displayed or non-displayed liquidity providing orders. Every Member would benefit from the availability of more liquidity on the Exchange that the proposed fees are designed to incentivize. The related and conforming changes are designed, as discussed in the Purpose and Statutory Basis sections, to provide additional clarity and remove superfluous provisions. Accordingly, the Exchange does not believe that these changes will have any impact on competition that is not necessary or appropriate in furtherance of the purposes of the Act.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

Written comments were neither solicited nor received.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

The foregoing rule change has become effective pursuant to section 19(b)(3)(A)(ii)²⁸ of the Act.

At any time within 60 days of the filing of the proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act. If the Commission takes such action, the Commission shall institute proceedings under section 19(b)(2)(B)²⁹ of the Act to determine whether the proposed rule change should be approved or disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's internet comment form (<http://www.sec.gov/rules/sro.shtml>); or
- Send an email to rule-comments@sec.gov. Please include File Number SR-IEX-2022-09 on the subject line.

Paper Comments

- Send paper comments in triplicate to Vanessa Countryman, Secretary,

Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549-1090.

All submissions should refer to File Number SR-IEX-2022-09. This file number should be included in the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's internet website (<http://www.sec.gov/rules/sro.shtml>). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for website viewing and printing in the Commission's Public Reference Section, 100 F Street NE, Washington, DC 20549, on official business days between the hours of 10:00 a.m. and 3:00 p.m. Copies of the filing will also be available for inspection and copying at the IEX's principal office. All comments received will be posted without change. Persons submitting comments are cautioned that we do not redact or edit personal identifying information from comment submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR-IEX-2022-09 and should be submitted on or before December 13, 2022.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.³⁰

Sherry R. Haywood,
Assistant Secretary.

[FR Doc. 2022-25355 Filed 11-21-22; 8:45 am]

BILLING CODE 8011-01-P

SECURITIES AND EXCHANGE COMMISSION

[SEC File No. 270-265, OMB Control No. 3235-0273]

Submission for OMB Review; Comment Request; Extension: Rule 17Ad-10

Upon Written Request, Copies Available From: Securities and Exchange Commission, Office of FOIA Services, 100 F Street NE, Washington, DC 20549-2736

Notice is hereby given that pursuant to the Paperwork Reduction Act of 1995 ("PRA") (44 U.S.C. 3501 *et seq.*), the Securities and Exchange Commission ("Commission") has submitted to the Office of Management and Budget ("OMB") a request for approval of extension of the previously approved collection of information provided for in Rule 17Ad-10 (17 CFR 240.17Ad-10), under the Securities Exchange Act of 1934 (15 U.S.C. 78a *et seq.*).

Rule 17Ad-10 generally requires registered transfer agents to: (1) create and maintain current and accurate securityholder records; (2) promptly and accurately record all transfers, purchases, redemptions, and issuances, and notify their appropriate regulatory agency if they are unable to do so; (3) exercise diligent and continuous attention in resolving record inaccuracies; (4) disclose to the issuers for whom they perform transfer agent functions and to their appropriate regulatory agency information regarding record inaccuracies; (5) buy-in certain record inaccuracies that result in a physical over issuance of securities; and (6) communicate with other transfer agents related to the same issuer. These requirements assist in the creation and maintenance of accurate securityholder records, enhance the ability to research errors, and ensure the transfer agent is aware of the number of securities that are properly authorized by the issuer, thereby avoiding over issuance.

The rule also has specific recordkeeping requirements. It requires registered transfer agents to retain certificate detail that has been deleted for six years and keep current an accurate record of the number of shares or principal dollar amount of debt securities that the issuer has authorized to be outstanding. These mandatory requirements ensure accurate securityholder records and assist the Commission and other regulatory agencies with monitoring transfer agents and ensuring compliance with the rule. This rule does not involve the collection of confidential information.

There are approximately 401 registered transfer agents. We estimate that the average number of hours necessary for each transfer agent to comply with Rule 17Ad-10 is approximately 80 hours per year, which generates an industry-wide annual burden of approximately 32,080 hours (401 times 80 hours). This burden is primarily of a recordkeeping nature but also includes a small amount of third party disclosure. At an average staff cost of \$50 per hour, the industry-wide internal labor cost of compliance (a monetization of the burden hours) is

²⁸ 15 U.S.C. 78s(b)(3)(A)(ii).

²⁹ 15 U.S.C. 78s(b)(2)(B).

³⁰ 17 CFR 200.30-3(a)(12).

approximately \$1,604,000 per year ($32,080 \times \50).

In addition, we estimate that each transfer agent will incur an annual external cost burden of approximately \$18,000 resulting from the collection of information. Therefore, the total annual external cost on the entire transfer agent industry is approximately \$7,218,000 (\$18,000 times 401). This cost primarily reflects ongoing computer operations and maintenance associated with generating, maintaining, and disclosing or providing certain information required by the rule.

The amount of time any particular transfer agent will devote to Rule 17Ad-10 compliance will vary according to the size and scope of the transfer agent's business activity. We note, however, that at least some of the records, processes, and communications required by Rule 17Ad-10 would likely be maintained, generated, and used for transfer agent business purposes even without the rule.

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information under the PRA unless it displays a currently valid OMB control number.

The public may view background documentation for this information collection at the following website: www.reginfo.gov. Find this particular information collection by selecting "Currently under 30-day Review—Open for Public Comments" or by using the search function. Written comments and recommendations for the proposed information collection should be sent by December 22, 2022 to (i) www.reginfo.gov/public/do/PRAMain and (ii) David Bottom, Director/Chief Information Officer, Securities and Exchange Commission, c/o John Pezzullo, 100 F Street NE, Washington, DC 20549, or by sending an email to: PRA_Mailbox@sec.gov.

Dated: November 16, 2022.

Sherry R. Haywood,

Assistant Secretary.

[FR Doc. 2022-25346 Filed 11-21-22; 8:45 am]

BILLING CODE 8011-01-P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34-96330; File No. SR-BX-2022-022]

Self-Regulatory Organizations; Nasdaq BX, Inc.; Notice of Filing and Immediate Effectiveness of Proposed Rule Change To Amend Rule BX Equity 6, Section 5 To Provide Participants With Additional Optional Settings

November 16, 2022.

Pursuant to section 19(b)(1) of the Securities Exchange Act of 1934 ("Act"),¹ and Rule 19b-4 thereunder,² notice is hereby given that on November 10, 2022, Nasdaq BX, Inc. ("BX" or "Exchange") filed with the Securities and Exchange Commission ("Commission") the proposed rule change as described in Items I, II, and III, below, which Items have been prepared by the Exchange. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange proposes to amend Rule BX Equity 6, Section 5 (Exchange Sharing of Participant Risk Settings) to provide Participants with additional optional settings.

The text of the proposed rule change is available on the Exchange's website at <https://listingcenter.nasdaq.com/rulebook/bx/rules>, at the principal office of the Exchange, and at the Commission's Public Reference Room.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the Exchange included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant aspects of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

The purpose of the proposed rule changes under Rule BX Equity 6, Section 5 (Exchange Sharing of Participant Risk Settings) is to provide BX Participants (the "Participants") with additional optional settings to assist them in their efforts to manage risk on their order flow. These additional settings provide participants with extra oversight and controls on orders coming into the exchange. Once the optional risk controls are set, the Exchange is authorized to take automated action if a designated risk level for a Participant is exceeded. Such risk settings would provide Participants with enhanced abilities to manage their risk with respect to orders on the Exchange.

All proposed risk settings are optional for Participants and afford flexibility to Participants to select their own risk tolerance levels. The proposed new and amended risk settings are as follows.

The Exchange is proposing to add an additional risk setting titled "Restricted Stock List." This control allows a Participant to restrict the types of securities transacted by setting a list of symbols for which orders cannot be entered. This control also allows Participants to set a hard to borrow list, which is a list of symbols for which short sale orders may not be entered. Short sale orders for symbols not on the hard to borrow list will be accepted; however, Participants will have an option to indicate that short sales orders are permitted for all symbols by not maintaining a hard to borrow list. This setting is similar to Interpretations and Policies .01(d) of BZX Rule 11.13.³

The Exchange is proposing to add an additional risk setting titled "ADV Check." This control relates to the size of an order as compared to the 20 day consolidated average daily volume⁴ (ADV) of the security and allows a Participant to set a specified percent of ADV that an order size cannot exceed. This control also allows a Participant to specify the minimum value on which such control is based if the average daily volume of the securities is below such value. This setting is similar to

³ See Securities Exchange Act Release No. 80611 (May 5, 2017) 82 FR 22045 (May 11, 2017) (SR-BatsBZX-2017-24).

⁴ In certain circumstances, when the security does not have 20 days of trading history, the ADV Check is calculated on fewer than 20 data points.

¹ 15 U.S.C. 78s(b)(1).

² 17 CFR 240.19b-4.

Interpretations and Policies .01(g) of BZX Rule 11.13.

The Exchange is proposing to add an additional risk setting titled “Fat Finger Protection.” This control relates to the limit price of an order as compared to the NBBO and includes both percentage-based and dollar-based controls. If the limit price of an order deviates from the NBBO in excess of the amount set by a Participant (either percentage or dollar based), the order will not be accepted. This setting is similar to Interpretations and Policies .01(b) of BZX Rule 11.13.

The Exchange is proposing to add an additional risk setting titled “Rate Thresholds Check.” A Participant will be able to set the maximum number of messages (other than cancellations, but including new orders, replacement orders and modifications) that can be sent in during a configurable one second time window set by the Exchange. This control can be set as a port level or per symbol. This setting is similar to Interpretations and Policies .01(f) of BZX Rule 11.13.

The Exchange is proposing to add an additional risk setting titled “Gross Exposure Check.” This control measures open, executed, or notional exposure of a Participant on the Exchange; and, when breached, prevents submission of all new orders and, optionally, will cancel all open orders. Gross open order exposure is measured as the sum of booked price times size for all open orders plus the sum of booked price times size for all open sell orders. Gross executed order exposure is measured as the sum of all executed buy and sell orders. Gross notional order exposure is measured as the sum of the gross open exposure and gross executed exposure. This setting is similar to Interpretations and Policies .01(h) of BZX Rule 11.13.

The Exchange is proposing to add an additional risk setting titled “Market Impact Check.” This optional control, if enabled, will result in the rejection of a Participant’s incoming limit order if the limit price of the order is priced through the far-side of the current LULD bands. In other words, a buy (sell) order cannot be priced more aggressively than the upper (lower) LULD band.⁵ The Exchange notes that pursuant to the existing LULD requirements, buy orders priced below the lower price bands (and

vice versa for sell orders) will be accepted and are eligible for inclusion in the NBBO; however, these orders are outside the price bands and will be non-executable. If the price bands move in such a way that an order that was previously outside the price band is now inside the band, the order will become executable.

The Exchange believes that this new optional setting is similar to the Exchange’s existing Limit Order Protection (“LOP”). LOP is a feature of the BX that prevents certain Limit Orders at prices outside of pre-set standard limits (“LOP Limit”) from being accepted by the System.⁶ LOP is operational each trading day. LOP does not apply in the event that there is no established LOP Reference Price.⁷ LOP is applicable on all order entry protocols.⁸ While the current LULD functionality would continue to apply, this additional proposed risk setting would allow a Participant to manage its risk more comprehensively.

The Exchange is also proposing to amend two existing risk settings titled, ISO Control and Duplication Control.

Currently, pursuant to BX Equity 6, Section 5(j), the Duplication control will automatically reject an order that a Participant submits to the Exchange to the extent that it is duplicative of another order that the Participant submitted to the Exchange during the prior five seconds. The Exchange proposes to provide additional flexibility for Participants by allowing the interval applicable to this risk check to vary from one to thirty seconds, as set by a Participant. This setting is similar to Interpretations and Policies .01(e) of BZX Rule 11.13.

Pursuant to BX Equity 6, Section 5(b), ISO Control setting prevents a Participant from entering an ISO order onto the Exchange. The Exchange proposes to expand this setting to allow a Participant to restrict additional order types from being entered. Specifically, a Participant may restrict their ability to place any of the following: ISO Orders (as currently provided by this risk setting), short sale orders, non-auction market orders, pre-market orders or post-market orders. The Exchange proposes to change the title of this risk

setting to Order Type/Attribution Check to better reflect its substance, as amended. This setting is similar to Interpretations and Policies .01(c) of BZX Rule 11.13.

As currently provided for existing risk settings, the Exchange will share any Participant risk settings in the trading system that are specified Rule BX Equity 6, Section 5, with the clearing member that clears transactions on behalf of the Participant even if the clearing member is not designated.

Implementation

The Exchange intends to implement of the proposed rule changes on or before March 31, 2023. The Exchange will issue an Equity Trader Alert to members announcing the exact date the Exchange will implement the risk protections.

2. Statutory Basis

The Exchange believes that its proposal is consistent with Section 6(b) of the Act,⁹ in general, and furthers the objectives of Section 6(b)(5) of the Act,¹⁰ in particular, in that it is designed to promote just and equitable principles of trade, to remove impediments to and perfect the mechanism of a free and open market and a national market system, and, in general to protect investors and the public interest.

Specifically, the Exchange believes the proposed amendment will remove impediments to and perfect the mechanism of a free and open market and a national market system because it provides functionality for a Participant to manage its risk exposure, while also maintaining a notification system under Rule BX Equity 6, Section 5 that would help to ensure the Participant and its clearing member are aware of developing issues.

A clearing member guarantees transactions executed on BX for members with whom it has entered into a clearing arrangement, and therefore bears the risk associated with those transactions. The Exchange therefore believes that it is appropriate for the clearing member to have knowledge of what risk settings the Participant may utilize within the Exchange’s trading system, as well as the option to set and adjust the risk levels. The proposal will permit clearing members who have a financial interest in the risk settings of Participants with whom the Participants have entered into clearing arrangements to better monitor and manage the potential risks assumed by clearing members, thereby providing clearing

⁵ The Limit Up-Limit Down (LULD) mechanism is intended to prevent trades in National Market System (NMS) securities from occurring outside of specified price bands. The bands are set at a percentage level above and below the average reference price of the security over the immediately preceding five-minute period. To accommodate fundamental price moves, there is a five-minute trading pause if trading is unable to occur within the specified price band after 15 seconds.

⁶ The LOP Limit is the greater of 10% of the LOP Reference Price or \$0.50 for all securities across all trading sessions. The LOP Reference Price is the current National Best Bid or Best Offer, the bid for sell orders and the offer for buy orders.

⁷ For example, if there is a one-sided quote or if the NBB, when used as the LOP Reference Price, is equal to or less than \$0.50.

⁸ BX maintains several communications protocols for Participants to use in entering Orders and sending other messages, such as: OUCH, RASH, QIX, FLITE and FIX.

⁹ 15 U.S.C. 78f(b).

¹⁰ 15 U.S.C. 78f(b)(5).

members with greater control and flexibility over setting their own risk tolerance and exposure and aiding clearing members in complying with the Act.

In addition, the Exchange believes that the proposed amendments under Rule BX Equity 6, Section 5, are designed to protect investors and the public interest because the proposed functionalities are a form of risk mitigation that will aid Participants and clearing members in minimizing their financial exposure and reduce the potential for disruptive, market-wide events. The proposed new:

- Gross Executed Check settings are appropriate measures to serve as an additional tool for Participants and clearing members to assist them in identifying open, executed, or notional exposure risk;
- Market Impact Check and ADV check may assist Participants in avoiding placing orders with unintentional market impact;
- Rate Thresholds Check may help alert a Participant to excessive message traffic that could affect technical port performance;
- Fat Finger Protection will assist a Participant in avoiding submission of orders with unintended price limits or share sizes;
- Restricted Stock List will assist a Participant in limiting trading for a particular security.

The proposed amendments to ISO Control will a Participant prevent trading in a particular order type by expanding the types of orders subject to this check to pre-market, post-market, short sales, non-auction market orders. The proposed amendments to the Duplication Control will allow a Participant additional flexibility in using this control by letting a Participant to choose the period of time over which this control applies.

The Exchange also believes the proposed amendments will assist Participants and clearing members in managing their financial exposure which, in turn, could enhance the integrity of trading on the securities markets and help to assure the stability of the financial system.

Finally, the Exchange believes that the proposed rule changes do not unfairly discriminate among the Exchange's Participants because use of the risk settings under Rule BX Equity 6, Section 5 are optional and available to all Participants, and not a prerequisite for participation on the Exchange.

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that the proposed rule change will impose any burden on competition not necessary or appropriate in furtherance of the purposes of the Act. In fact, the Exchange believes that the proposal will have a positive effect on competition because, it would allow the Exchange to offer risk management functionality that is comparable to functionality being offered by other national securities exchanges. Moreover, by providing Participants and their clearing members additional means to monitor and control risk, the proposed rule may increase confidence in the proper functioning of the markets and contribute to additional competition among trading venues and broker-dealers. Rather than impede competition, the proposal is designed to facilitate more robust risk management by Participants and clearing members, which, in turn, could enhance the integrity of trading on the securities markets and help to assure the stability of the financial system.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

No written comments were either solicited or received.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

Because the foregoing proposed rule change does not: (i) significantly affect the protection of investors or the public interest; (ii) impose any significant burden on competition; and (iii) become operative for 30 days from the date on which it was filed, or such shorter time as the Commission may designate, it has become effective pursuant to Section 19(b)(3)(A)(iii) of the Act¹¹ and subparagraph (f)(6) of Rule 19b-4 thereunder.¹²

At any time within 60 days of the filing of the proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act. If the

Commission takes such action, the Commission shall institute proceedings to determine whether the proposed rule should be approved or disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's internet comment form (<http://www.sec.gov/rules/sro.shtml>); or
- Send an email to rule-comments@sec.gov. Please include File Number SR-BX-2022-022 on the subject line.

Paper Comments

- Send paper comments in triplicate to Secretary, Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549-1090.

All submissions should refer to File Number SR-BX-2022-022. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's internet website (<http://www.sec.gov/rules/sro.shtml>). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for website viewing and printing in the Commission's Public Reference Room, 100 F Street NE, Washington, DC 20549, on official business days between the hours of 10:00 a.m. and 3:00 p.m. Copies of the filing also will be available for inspection and copying at the principal office of the Exchange. All comments received will be posted without change. Persons submitting comments are cautioned that we do not redact or edit personal identifying information from comment submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR-BX-2022-022 and should be submitted on or before December 13, 2022.

¹¹ 15 U.S.C. 78s(b)(3)(A)(iii).

¹² 17 CFR 240.19b-4(f)(6). In addition, Rule 19b-4(f)(6) requires a self-regulatory organization to give the Commission written notice of its intent to file the proposed rule change at least five business days prior to the date of filing of the proposed rule change, or such shorter time as designated by the Commission. The Exchange has satisfied this requirement.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.¹³

Sherry R. Haywood,

Assistant Secretary.

[FR Doc. 2022-25354 Filed 11-21-22; 8:45 am]

BILLING CODE 8011-01-P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34-96337; File No. 10-239]

24X National Exchange LLC; Notice of Filing of Amendment No. 2 to an Application for Registration as a National Securities Exchange Under Section 6 of the Securities Exchange Act of 1934

November 17, 2022.

On March 25, 2022, 24X National Exchange LLC (“24X”) filed with the Securities and Exchange Commission (“Commission”) a Form 1 application under the Securities Exchange Act of 1934 (“Act”) seeking registration as a national securities exchange under Section 6 of the Act.¹ Notice of the application was published for comment in the **Federal Register** on June 6, 2022.² The Commission received three comment letters on 24X’s Initial Form 1 Application and a letter from 24X responding to these comment letters.³ On September 1, 2022, the Commission instituted proceedings pursuant to Section 19(a)(1)(B) of the Act⁴ to determine whether to grant or deny 24X’s application for registration as a national securities exchange under Section 6 of the Act (the “OIP”).⁵ The Commission received one comment letter in response to the OIP,⁶ and a letter in response to the OIP from 24X.⁷ On October 21, 2022, 24X filed an amendment to its Initial Form 1

Application (“Amendment No. 1”).⁸ Notice of Amendment No. 1 was published for comment in the **Federal Register** on November 9, 2022.⁹ On November 10, 2022, 24X filed a second amendment to its Initial Form 1 Application (“Amendment No. 2”).¹⁰ The Commission is publishing this notice in order to solicit views of interested persons on 24X’s Initial Form 1 Application, as amended by Amendment No. 1 and Amendment No. 2.

I. Description of 24X’s Proposed Trading System

24X proposes to operate a fully automated electronic trading platform for the trading of listed NMS stocks pursuant to unlisted trading privileges.¹¹ 24X would not maintain a physical trading floor.¹² 24X proposes to allow trading in NMS stocks 24 hours a day, 7 days per week, 365 days a year.¹³ 24X proposes specific rules to govern trading during regular trading hours¹⁴ as well as trading outside of regular trading hours.¹⁵

II. Amendment No. 2 to 24X’s Initial Form 1 Application

In Amendment No. 2, 24X proposes certain changes to the Amended and Restated Limited Liability Company Operating Agreement of 24X Bermuda Holdings LLC,¹⁶ as well as to the Member Nominating Committee Charter.¹⁷

III. Request for Written Comment

The Commission requests that interested persons provide written views and data with respect to 24X’s

Initial Form 1 Application, as amended by Amendment No. 1 and Amendment No. 2. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission’s internet comment form (<http://www.sec.gov/rules/sro.shtml>); or
- Send an email to rule-comments@sec.gov. Please include File Number 10-239 on the subject line.

Paper Comments

- Send paper comments in triplicate to Secretary, Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549-1090.

All submissions should refer to File Number 10-239. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission’s internet website (<http://www.sec.gov/rules/other.shtml>). Copies of the submission, all subsequent amendments, all written statements with respect to 24X’s Initial Form 1 Application, as amended by Amendment No. 1 and Amendment No. 2, filed with the Commission, and all written communications relating to the application between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for website viewing and printing in the Commission’s Public Reference Room, 100 F Street NE, Washington, DC 20549, on official business days between the hours of 10:00 a.m. and 3:00 p.m. All comments received will be posted without change. Persons submitting comments are cautioned that we do not redact or edit personal identifying information from submissions. You should submit only information that you wish to make publicly available.

All submissions should refer to File Number 10-239 and should be submitted on or before December 13, 2022.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.¹⁸

Sherry R. Haywood,

Assistant Secretary.

[FR Doc. 2022-25425 Filed 11-21-22; 8:45 am]

BILLING CODE 8011-01-P

¹⁸ 17 CFR 200.30-3(a)(71)(ii).

¹³ 17 CFR 200.30-3(a)(12).

¹⁵ U.S.C. 78f.

² See Securities Exchange Act Release No. 95007 (May 31, 2022), 87 FR 34333 (June 6, 2022) (“Initial Form 1 Application”).

³ The public comment file for 24X’s Form 1 application (File No. 10-239) is available on the Commission’s website at: <https://www.sec.gov/comments/10-239/10-239.htm>.

⁴ 15 U.S.C. 78s(a)(1)(B).

⁵ See Securities Exchange Act Release No. 95651 (Sept. 1, 2022), 87 FR 54736 (Sept. 7, 2022).

⁶ See letter from Brian Hyndman, President and Chief Executive Officer, Blue Ocean ATS, LLC, dated Sept. 28, 2022, to Vanessa A. Countryman, Secretary, Commission.

⁷ See letter from James M. Brady, Katten Muchin Rosenman LLP, outside counsel for 24X National Exchange LLC, dated Oct. 18, 2022, to Vanessa A. Countryman, Secretary, Commission.

⁸ Amendment No. 1 is available on the Commission’s website at: <https://www.sec.gov/rules/other/2022/24x/24x-form-1.htm>.

⁹ See Securities Exchange Act Release No. 96218 (Nov. 3, 2022), 87 FR 67725 (Nov. 9, 2022).

¹⁰ Amendment No. 2 is available on the Commission’s website at: <https://www.sec.gov/rules/other/2022/24x/24x-form-1.htm>.

¹¹ See Exhibit E, as amended by 24X’s Amendment No. 1, at 1, 4.

¹² *Id.* at 1.

¹³ See proposed 24X Rule 11.1 (describing the hours of trading and trading days for 24X).

¹⁴ Regulation NMS Rule 600(b)(77) defines “regular trading hours” as “the time between 9:30 a.m. and 4:00 p.m. Eastern Time . . .” 24X proposes to define four different trading sessions. See proposed 24X Rules 1.5(b), defining the “24X Market Session”; 1.5(k) defining the “Core Market Session”; 1.5(v) defining the “Post-market Session”; and 1.5(w) defining the “Pre-Market Session”.

¹⁵ See e.g., proposed 24X Rule 11.16 (describing what orders are eligible for execution outside of regular trading hours).

¹⁶ See Exhibits C and C-2, as amended by 24X’s Amendment No. 2.

¹⁷ See Exhibit J-3, as amended by 24X’s Amendment No. 2.

**SECURITIES AND EXCHANGE
COMMISSION**

[Release No. 34-96335; File No. SR-
CboeBZX-2022-043]

**Self-Regulatory Organizations; Cboe
BZX Exchange, Inc.; Notice of
Withdrawal of a Proposed Rule Change
To Amend Exchange Rule 14.11(d) To
Accommodate Exchange Listing and
Trading of Options-Linked Securities**

November 16, 2022.

On August 18, 2022, Cboe BZX Exchange, Inc. (“BZX” or “Exchange”) filed with the Securities and Exchange Commission (“Commission”), pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (“Act”),¹ and Rule 19b-4 thereunder,² a proposed rule change to amend BZX Rule 14.11(d) to accommodate the listing and trading of Options-Linked Securities.

The proposed rule change was published for comment in the **Federal Register** on September 8, 2022.³ On October 14, 2022, pursuant to Section 19(b)(2) of the Act,⁴ the Commission designated a longer period within which to approve the proposed rule change, disapprove the proposed rule change, or institute proceedings to determine whether to disapprove the proposed rule change.⁵ The Commission received no comment letters on the proposed rule change.

On November 10, 2022, the Exchange withdrew the proposed rule change (SR-CboeBZX-2022-043).

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.⁶

Sherry R. Haywood,
Assistant Secretary.

[FR Doc. 2022-25359 Filed 11-21-22; 8:45 am]

BILLING CODE 8011-01-P

**SECURITIES AND EXCHANGE
COMMISSION**

[Release No. 34-96333; File No. SR-
NYSEARCA-2022-77]

**Self-Regulatory Organizations; NYSE
Arca, Inc.; Notice of Filing and
Immediate Effectiveness of Proposed
Rule Change To Amend 6.41P-O**

November 16, 2022.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (“Act”),¹ and Rule 19b-4 thereunder,² notice is hereby given that, on November 9, 2022, NYSE Arca, Inc. (“NYSE Arca” or the “Exchange”) filed with the Securities and Exchange Commission (the “Commission”) the proposed rule change as described in Items I, II, and III below, which Items have been prepared by the self-regulatory organization. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

**I. Self-Regulatory Organization’s
Statement of the Terms of Substance of
the Proposed Rule Change**

The Exchange proposes to amend 6.41P-O (Price Reasonability Checks—Orders and Quotes). The proposed rule change is available on the Exchange’s website at www.nyse.com, at the principal office of the Exchange, and at the Commission’s Public Reference Room.

**II. Self-Regulatory Organization’s
Statement of the Purpose of, and
Statutory Basis for, the Proposed Rule
Change**

In its filing with the Commission, the self-regulatory organization included statements concerning the purpose of, and basis for, the proposed rule change and discussed any comments it received on the proposed rule change. The text of those statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant parts of such statements.

**A. Self-Regulatory Organization’s
Statement of the Purpose of, and the
Statutory Basis for, the Proposed Rule
Change**

1. Purpose

The Exchange proposes to amend Rule 6.41P-O (Price Reasonability Checks—Orders and Quotes) to modify

the application of certain risk checks on Pillar as set forth below.

The Exchange recently revised Rule 6.41P-O to clarify the application of the “Price Reasonability Checks” to orders and quotes, which include the Arbitrage Check and the Intrinsic Value Check (collectively, the “Checks”), when such Checks rely on last sale information.⁴ In particular, the Exchange modified the rule to reflect Pillar functionality that excluded from the Checks those transactions (such as odd lot transactions) that are not “last-sale eligible.” However, the Exchange has determined to modify the operation of the Checks under Pillar such that they apply to trades in underlying securities of any size, including odd lots.⁵ The Exchange believes that applying the Checks based on a broader range of underlying transactions—both round lots and odd lots—would enhance the efficacy of the Checks as this proposed functionality would provide a better representation of the trade prices occurring in the underlying market.⁶ As such, the Exchange believes that the proposed functionality would continue to provide price protection to OTP Holders and OTP Firms.

As proposed, the Arbitrage Check would reject or cancel (if resting) a buy order or quote for call options if the price of the order or quote is equal to or greater than the price of the last trade (of any size) of the underlying security on the Primary Market, plus a specified threshold to be determined by the Exchange and announced by Trader Update.⁷ Regarding the Intrinsic Value Check, the Exchange proposes that the Intrinsic Value of a put option would be equal to the strike price minus the price of the last trade (of any size) of the underlying security on the Primary Market” and the Intrinsic Value of a call option would be equal to the price of

⁴ See Rule 6.41P-O(b) and (c) (describing the Arbitrage Check and the Intrinsic Value Check, respectively). See Securities Exchange Act Release No. 95088 (June 13, 2022), 87FR 36556 (June 17, 2022) (SR-NYSEArca-2022-34) (immediately effective filing to modify Rule 6.41P-O(b) and (c) to use as a basis for the Check “the price of the last—sale eligible trade” of the underlying security, rather than the “last sale price” of the underlying security).

⁵ The Exchange notes, prior to migrating to Pillar, the Exchange included odd lots in its application of the Arbitrage Check and Intrinsic Value Check, per Rules 6.60-O (Price Protection—Orders) and 6.61-O (Price Protection—Quotes). See also NYSE American LLC (“NYSE American”) Rules 967NY (c)(1), (2) and 967.1NY (regarding the application of Arbitrage Checks and Intrinsic Value Checks to orders and quotes, respectively).

⁶ The Exchange notes that trades in higher-priced underlying securities tend to be odd lots, which highlights the importance of capturing such trades in the Checks.

⁷ See Rule 6.41P-O(b)(2).

¹ 15 U.S.C. 78s(b)(1).

² 17 CFR 240.19b-4.

³ See Securities Exchange Act Release No. 95655 (Sept. 1, 2022), 87 FR 55068.

⁴ 15 U.S.C. 78s(b)(2).

⁵ See Securities Exchange Act Release No. 96077, 87 FR 63830 (Oct. 20, 2022).

⁶ 17 CFR 200.30-3(a)(12).

¹ 15 U.S.C. 78s(b)(1).

² 15 U.S.C. 78a.

³ 17 CFR 240.19b-4.

the last trade (of any size) of the underlying security on the Primary Market minus the strike price.⁸

In addition, the Exchange proposes a conforming change to delete Rule 6.41P–O(a)(3)(iv) as no longer applicable, because the Checks would no longer impose a size/last sale eligible trade condition restriction on the underlying trade.⁹ The Exchange believes this proposed rule change would align with the proposed functionality and add clarity and transparency to Exchange rules making them easier to navigate and comprehend.

2. Statutory Basis

The proposed rule change is consistent with Section 6(b) of the Securities Exchange Act of 1934 (the “Act”),¹⁰ in general, and furthers the objectives of Section 6(b)(5),¹¹ in particular, because it is designed to prevent fraudulent and manipulative acts and practices, to promote just and equitable principles of trade, to foster cooperation and coordination with persons engaged in facilitating transactions in securities, to remove impediments to, and perfect the mechanism of, a free and open market and a national market system and, in general, to protect investors and the public interest.

The Exchange believes that the proposed rule change to modify the operation of the Checks to apply to transactions of any size—whether odd lots or round lots—would promote just and equitable principles of trade and remove impediments to and perfect the mechanism of a free and open market and a national market system and protect investors because the Checks would be applied to a broader spectrum of trade prices in underlying securities, which would enhance the efficacy of the Checks to the benefit of investors and the investing public. As such, the Exchange believes that the proposed functionality would continue to provide price protection to OTP Holders and OTP Firms.

The proposed non-substantive conforming changes would add clarity, transparency, and internal consistency to Exchange rules making them easier to comprehend.

B. Self-Regulatory Organization’s Statement on Burden on Competition

The Exchange does not believe that the proposed rule change will impose any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act. The proposed change is not intended to address competition, but rather to modify the operation of the Exchange’s Checks by accounting for trade prices in underlying transactions of any size (both odd lots and round lots), which would impact (and benefit) all similarly-situated market participants.

C. Self-Regulatory Organization’s Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

No written comments were solicited or received with respect to the proposed rule change.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

The Exchange has filed the proposed rule change pursuant to Section 19(b)(3)(A)(iii) of the Act¹² and Rule 19b–4(f)(6) thereunder.¹³ Because the proposed rule change does not (i) significantly affect the protection of investors or the public interest; (ii) impose any significant burden on competition; and (iii) become operative prior to 30 days from the date on which it was filed, or such shorter time as the Commission may designate, if consistent with the protection of investors and the public interest, the proposed rule change has become effective pursuant to Section 19(b)(3)(A)(iii) of the Act¹⁴ and Rule 19b–4(f)(6)(iii) thereunder.¹⁵

A proposed rule change filed under Rule 19b–4(f)(6)¹⁶ normally does not become operative prior to 30 days after the date of the filing. However, pursuant to Rule 19b4(f)(6)(iii),¹⁷ the Commission may designate a shorter time if such action is consistent with the protection of investors and the public interest. The Exchange has asked the Commission to waive the 30-day operative delay so that the proposal may take effect

immediately. The Commission believes that waiver of the operative delay is consistent with the protection of investors and the public interest because it will provide enhanced price protection checks to market participants without delay. Accordingly, the Commission hereby waives the 30-day operative delay and designates the proposal operative upon filing.¹⁸

At any time within 60 days of the filing of such proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act. If the Commission takes such action, the Commission shall institute proceedings under Section 19(b)(2)(B)¹⁹ of the Act to determine whether the proposed rule change should be approved or disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission’s internet comment form (<http://www.sec.gov/rules/sro.shtml>); or
- Send an email to rule-comments@sec.gov. Please include File Number SR–NYSEARCA–2022–77 on the subject line.

Paper Comments

- Send paper comments in triplicate to: Secretary, Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549–1090. All submissions should refer to File Number SR–NYSEARCA–2022–77. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission’s internet website (<http://www.sec.gov/rules/sro.shtml>). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the

¹² 15 U.S.C. 78s(b)(3)(A)(iii).

¹³ 17 CFR 240.19b–4(f)(6).

¹⁴ 15 U.S.C. 78s(b)(3)(A)(iii).

¹⁵ 17 CFR 240.19b–4(f)(6). In addition, Rule 19b–4(f)(6)(iii) requires a self-regulatory organization to give the Commission written notice of its intent to file the proposed rule change, along with a brief description and text of the proposed rule change, at least five business days prior to the date of filing of the proposed rule change, or such shorter time as designated by the Commission. The Exchange has fulfilled this requirement.

¹⁶ 17 CFR 240.19b–4(f)(6).

¹⁷ 17 CFR 240.19b–4(f)(6)(iii).

⁸ See Rule 6.41P–O(c)(1), (2).

⁹ See proposed Rule 6.41P–O(a)(3). The Exchange also proposes to make non-substantive conforming changes to this paragraph, including by renumbering, which changes add clarity, transparency, and internal consistency to Exchange rules. See *id.*

¹⁰ 15 U.S.C. 78f(b).

¹¹ 15 U.S.C. 78f(b)(5).

¹⁸ For purposes only of accelerating the operative date of this proposal, the Commission has considered the proposed rule’s impact on efficiency, competition, and capital formation. 15 U.S.C. 78c(f).

¹⁹ 15 U.S.C. 78s(b)(2)(B).

Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for website viewing and printing in the Commission's Public Reference Room, 100 F Street NE, Washington, DC 20549 on official business days between the hours of 10:00 a.m. and 3:00 p.m. Copies of the filing also will be available for inspection and copying at the principal office of the Exchange. All comments received will be posted without change. Persons submitting comments are cautioned that we do not redact or edit personal identifying information from comment submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR-NYSEARCA-2022-77 and should be submitted on or before December 13, 2022.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.²⁰

Sherry R. Haywood,
Assistant Secretary.

[FR Doc. 2022-25357 Filed 11-21-22; 8:45 am]

BILLING CODE 8011-01-P

SMALL BUSINESS ADMINISTRATION

[Disaster Declaration #17706 and #17707;
TEXAS Disaster Number TX-00645]

Administrative Declaration of a Disaster for the State of Texas

AGENCY: Small Business Administration.

ACTION: Notice.

SUMMARY: This is a notice of an Administrative declaration of a disaster for the State of Texas dated 11/16/2022.

Incident: Severe Storms and Tornadoes.

Incident Period: 11/04/2022.

DATES: Issued on 11/16/2022.

Physical Loan Application Deadline Date: 01/17/2023.

Economic Injury (EIDL) Loan Application Deadline Date: 08/16/2023.

ADDRESSES: Submit completed loan applications to: U.S. Small Business Administration, Processing and Disbursement Center, 14925 Kingsport Road, Fort Worth, TX 76155.

FOR FURTHER INFORMATION CONTACT: A. Escobar, Office of Disaster Assistance, U.S. Small Business Administration,

409 3rd Street SW, Suite 6050, Washington, DC 20416, (202) 205-6734.

SUPPLEMENTARY INFORMATION: Notice is hereby given that as a result of the Administrator's disaster declaration, applications for disaster loans may be filed at the address listed above or other locally announced locations.

The following areas have been determined to be adversely affected by the disaster:

Primary Counties: Lamar, Morris.

Contiguous Counties:

Texas: Bowie, Camp, Cass, Delta, Fannin, Franklin, Marion, Red River, Titus, Upshur.

Oklahoma: Bryan, Choctaw.

The Interest Rates are:

	Percent
<i>For Physical Damage:</i>	
Homeowners with Credit Available Elsewhere	4.625
Homeowners without Credit Available Elsewhere	2.313
Businesses with Credit Available Elsewhere	6.610
Businesses without Credit Available Elsewhere	3.305
Non-Profit Organizations with Credit Available Elsewhere ...	2.375
Non-Profit Organizations without Credit Available Elsewhere	2.375
<i>For Economic Injury:</i>	
Businesses & Small Agricultural Cooperatives without Credit Available Elsewhere	3.305
Non-Profit Organizations without Credit Available Elsewhere	2.375

The number assigned to this disaster for physical damage is 17706 C and for economic injury is 17707 O.

The States which received an EIDL Declaration # is Oklahoma, Texas.

(Catalog of Federal Domestic Assistance Number 59008)

Dated: November 16, 2022.

Isabella Guzman,
Administrator.

[FR Doc. 2022-25437 Filed 11-21-22; 8:45 am]

BILLING CODE 8026-09-P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

Aviation Rulemaking Advisory Committee; Meeting

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of Aviation Rulemaking Advisory Committee (ARAC) meeting.

SUMMARY: This notice announces a meeting of the ARAC.

DATES: The meeting will be held on Thursday, December 8, 2022, from 9 a.m. to 12 p.m. Pacific Time.

Requests to attend the meeting must be received by Monday, November 21, 2022.

Requests for accommodations to a disability must be received by November 21, 2022.

Requests to submit written materials to be reviewed during the meeting must be received no later than Monday, November 21, 2022.

ADDRESSES: The meeting will be held at the NASA AMES Conference Center Building 3, 500 Severins Avenue, Moffett Field, CA 94035, and virtually on Microsoft Teams. However, if the FAA is unable to hold the meeting in person due to circumstances outside of its control, the FAA will hold a virtual meeting and notify registrants with the meeting details and post any updates on the FAA Committee website. Members of the public who wish to observe the meeting must RSVP by emailing 9-awarac@faa.gov. General committee information including copies of the meeting minutes will be available on the FAA Committee website at https://www.faa.gov/regulations_policies/rulemaking/committees/documents/.

FOR FURTHER INFORMATION CONTACT: Lakisha Pearson, Federal Aviation Administration, 800 Independence Avenue SW, Washington, DC 20591, telephone (202) 267-4191; email 9-awarac@faa.gov. Any committee-related request should be sent to the person listed in this section.

SUPPLEMENTARY INFORMATION:

I. Background

ARAC was created under the Federal Advisory Committee Act (FACA), in accordance with Title 5 of the United States Code (5 U.S.C. App. 2) to provide advice and recommendations to the FAA concerning rulemaking activities, such as aircraft operations, airman and air agency certification, airworthiness standards and certification, airports, maintenance, noise, and training.

II. Agenda

At the meeting, the agenda will cover the following topics:

- Status Report from the FAA
- Status Updates:
 - Active Working Groups
 - Transport Airplane and Engine (TAE) Subcommittee
- Recommendation Reports
- Any Other Business

The detailed agenda will be posted on the FAA Committee website address listed in the **ADDRESSES** section at least one week in advance of the meeting.

²⁰ 17 CFR 200.30-3(a)(12).

III. Public Participation

The meeting will be open to the public for virtual or in person attendance on a first-come, first served basis, as space is limited. Please confirm your attendance with the person listed in the **FOR FURTHER INFORMATION CONTACT** section and provide the following information: full legal name, country of citizenship, and name of your industry association or applicable affiliation. When registration is confirmed, FAA will email registrants the meeting access information in a timely manner prior to the meeting.

The U.S. Department of Transportation is committed to providing equal access to this meeting for all participants. If you need alternative formats or services because of a disability, such as sign language, interpretation, or other ancillary aids, please contact the person listed in the **FOR FURTHER INFORMATION CONTACT** section.

The FAA is not accepting oral presentations at this meeting due to time constraints. Any member of the public may present a written statement to the committee at any time. The public may present written statements to ARAC by providing a copy to the Designated Federal Officer via the email listed in the **FOR FURTHER INFORMATION CONTACT** section.

Issued in Washington, DC, on November 16, 2022.

Brandon Roberts,

Executive Director, Office of Rulemaking.

[FR Doc. 2022-25325 Filed 11-21-22; 8:45 am]

BILLING CODE 4910-13-P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

[Docket No. 2022-1564]

Agency Information Collection

Activities: Requests for Comments; Clearance of a Renewed Approval of Information Collection: Certification of Aircraft and Airmen for the Operation of Light-Sport Aircraft

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice and request for comments.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995, FAA invites public comments about our intention to request the Office of Management and Budget (OMB) approval to renew an information collection. The collection involves the recordkeeping requirement for owners/

operators of aircraft issued a special airworthiness certificate in the light-sport aircraft category (SLSA) to keep the current status of applicable safety directives, and transfer these records with the aircraft at the time the aircraft is sold. The information to be collected is necessary to determine and ensure the SLSA aircraft is in a condition for safe flight prior to aircraft operation. The title of this collection is being revised from Certification of Aircraft and Airmen for the Operation of Light-Sport Aircraft to Special Light-Sport Aircraft (SLSA) Safety Directive Recordkeeping, to better reflect the purpose of the information collected.

DATES: Written comments should be submitted by January 23, 2023.

ADDRESSES: Please send written comments:

By Electronic Docket:

www.regulations.gov (Enter docket number into search field)

By email: Tanya Glines, tanya.glines@faa.gov

FOR FURTHER INFORMATION CONTACT:

Tanya Glines by email at: Tanya.glines@faa.gov; phone: 202-380-5896.

SUPPLEMENTARY INFORMATION:

Public Comments Invited: You are asked to comment on any aspect of this information collection, including (a) whether the proposed collection of information is necessary for FAA's performance; (b) the accuracy of the estimated burden; (c) ways for FAA to enhance the quality, utility and clarity of the information collection; and (d) ways that the burden could be minimized without reducing the quality of the collected information. The agency will summarize and/or include your comments in the request for OMB's clearance of this information collection.

OMB Control Number: 2120-0730.

Title: Certification of Aircraft and Airmen for the Operation of Light-Sport Aircraft.

Form Numbers: Aircraft maintenance records/logs.

Type of Review: Renewal of an information collection.

Background: Title 14 CFR, § 91.417(a)(2)(v) requires each registered owner or operator to retain records containing the current status of applicable safety directives including, for each, the method of compliance, the safety directive number and revision date. Additionally, if the safety directive involves recurring action, the time and date when the next action is required.

Recording this information and retaining these records is necessary to determine if unsafe conditions have been corrected on aircraft issued a

special airworthiness certificate in the light-sport category (SLSA), which assists in ensuring that the SLSA aircraft is in a condition safe for flight prior to its operation within the national airspace.

Respondents include owners/operators of SLSA, aircraft mechanics, and LSA repairmen with a Maintenance rating. The records of SLSA safety directive compliance are retained by the aircraft owner/operator, who must keep the records for the life of the SLSA aircraft and transfer them to the new owner at the time the aircraft is sold. The burden estimates are based on the current number of registered SLA and a projected future growth rate.

Respondents: 3224 owners/operators of SLSA aircraft.

Frequency: On occasion.

Estimated Average Burden per

Response: 2 Hours.

Estimated Total Annual Burden: 6,448 hours of annual burden.

Issued in Washington, DC, on November 16, 2022.

Tanya A. Glines,

Aviation Safety Inspector, Office of Safety Standards, Aircraft Maintenance Division, Airmen Section.

[FR Doc. 2022-25350 Filed 11-21-22; 8:45 am]

BILLING CODE 4910-13-P

DEPARTMENT OF TRANSPORTATION

Federal Highway Administration

Environmental Impact Statement; Maui, Hawaii

AGENCY: Federal Highway Administration (FHWA), Department of Transportation (DOT).

ACTION: Notice of intent to prepare an environmental impact statement.

SUMMARY: The FHWA, in coordination with the Hawaii Department of Transportation (HDOT), is issuing this notice to invite comment and advise the public that an Environmental Impact Statement (EIS) will be prepared to study potential improvements to the Honoapiilani Highway (State Route No. 30) between Ukumehame and Launiupoko in West Maui. Improvements are needed to provide a reliable transportation facility that would not be inundated by the predicted 3.2-foot sea level rise and undermined by coastal erosion. The FHWA, as the Federal lead agency, and HDOT as the project sponsor and joint lead agency, will prepare an EIS for the Honoapiilani Highway Improvements Project, Ukumehame to Launiupoko, covering the 6-mile segment between

milepost 11 in the vicinity of Papalaua Wayside Park in Ukumehame (southeastern terminus) and milepost 17 in Launiupoko, where Honoapiilani Highway currently connects with the existing southern terminus of the Lahaina Bypass (northwestern terminus of the project).

DATES: Comments must be received by December 31, 2022. Written comments received by the submittal deadline will be published in the Draft EIS.

Public meetings will be held on December 14, 2022, and December 15, 2022. Meetings will be virtual and/or in-person. Please refer to the project website for meeting information. For public scoping information and requests, including special assistance requirements to participate fully in the meeting, please contact HDOT using the contact information in the **FOR FURTHER INFORMATION CONTACT** section below by December 7, 2022.

FOR FURTHER INFORMATION CONTACT: This NOI and Supplementary NOI Document are available on the project website:

www.Honoapiilani

HwyImprovements.com.

Please refer to the website for the latest information about public meetings and to submit written comments and questions on the project's preliminary Purpose and Need, scope, design alternatives, and other details pertinent to the EIS, as described in this NOI.

In addition, comments and questions may also be submitted via the following methods:

Mail: Federal Highway Administration, Hawaii Division
Attention: Richelle Takara, Division Administrator
Box 50206, 300 Ala Moana Blvd., Room 3-229 Honolulu, HI 96850. **Email:** Richelle.Takara@dot.gov, **Telephone:** (808) 541-2700.

Mail: Hawaii Department of Transportation, Highways Division
Attention: Genevieve Sullivan
869 Punchbowl Street, Room 301 Honolulu, HI 96813. **Email:** genevieve.h.sullivan@hawaii.gov, **Telephone:** (808) 587-1834.

Comments may also be offered during the public scoping meetings. Interested persons may request to be added to the project mailing list to receive notices of future project information. The Project website has a link to join the mailing list.

SUPPLEMENTARY INFORMATION:

The purpose of this Notice of Intent (NOI) is to:

1. Alert interested parties regarding the plan to prepare the EIS;
2. Provide information on the nature of the proposed project;
3. Invite participation in the EIS process, including comments on the

Purpose and Need for the project and the scope of the EIS proposed in this notice; and

4. Announce public scoping meetings.

As public involvement is crucial to the success of transportation projects, the FHWA and HDOT will consider all comments received in response to this notice and make revisions as appropriate. The EIS will be prepared in accordance with the requirements of the National Environmental Policy Act (NEPA) of 1969, as amended (42 U.S.C. 4321, *et seq.*), 23 U.S.C. 139 regarding efficient environmental reviews for project decision making and One Federal Decision, CEQ regulations implementing NEPA (40 CFR parts 1500–1508), FHWA regulations implementing NEPA (23 CFR part 771), and all applicable Federal, State, and local laws and regulations.

1. Project History

On June 7, 2007, FHWA published a NOI for an EIS in the **Federal Register** (72 FR 31649) to realign Honoapiilani Highway in West Maui. Project objectives for that proposal, involving a longer 11-mile segment of Honoapiilani Highway, were to increase roadway capacity, safety, and reliability. In addition, the previous Federally funded proposal sought to address the eroding shoreline between Maalaea on the southern end of West Maui and Launiupoko. However, the EIS was never completed, and FHWA rescinded the NOI on June 5, 2020 (85 FR 34712), citing the difficult terrain and the estimated high project construction cost.

In contrast with that rescinded project, HDOT's current proposal is a more focused project to address a shorter, 6-mile segment of the highway, which does not include the areas of steep terrain that previously proved to be cost prohibitive. The currently proposed project has been awarded a United States Department of Transportation (U.S. DOT) Rebuilding American Infrastructure with Sustainability and Equity (RAISE) Grant to assist with funding. The RAISE Grant funding does not predetermine the alternative selection.

In addition to the standard cardinal direction terms north, south, east, and west, this NOI uses common local naming conventions such as *mauka/makai* (towards the mountains/ocean) which correspond to generally easterly/westerly directions in this project area, the *pali* (cliff, but also refers to a specific place of steep topography south of the project area), and West Maui place names, such as Lahaina (a town to the north of the project area). Additional project background, maps, and

information to support the following NOI sections are provided in the Supplementary NOI Document.

2. Preliminary Purpose and Need

Public input received prior to developing this NOI supports the primary purpose of this project, which is to provide a reliable transportation facility in West Maui and improve Honoapiilani Highway's resilience by reducing the highway's vulnerability to coastal hazards. Specifically, the project is intended to address existing coastal erosion and flooding, as well as future coastal erosion and flooding caused by anticipated sea level rise, as delineated by the Hawaii Climate Change Mitigation and Adaptation Commission (HCCC)'s Sea Level Rise Exposure Area (SLR-XA), along the stretch of highway from Ukumehame to Launiupoko, approximately milepost 11 to milepost 17. Areas within the SLR-XA boundary, including Honoapiilani Highway, are considered exposed and potentially vulnerable to sea level rise. The 3.2-foot SLR-XA encroaches on roughly four (4) miles out of the six (6) miles of the existing highway in the project area. Therefore, the primary purpose of the project is to reduce the highway's exposure to the SLR-XA, where feasible. Secondary objectives include: (1) Provide Regional Transportation System Linkages that Support the Safe Movement of People and Goods, and (2) Conform with Regional Land Use and Transportation Plans. The project preliminary Purpose and Need, along with secondary objectives, and the range of reasonable alternatives may be modified, based on public input and interagency coordination during the NEPA review.

Highway service disruptions are expected to increase as the frequency and magnitude of flood occurrences are exacerbated by climate change and sea level rise. HCCC's SLR-XA boundary delineates the statewide footprint where passive flooding, annual high wave flooding, and coastal erosion has been modeled for the 0.5-foot, 1.1-foot, 2.0-foot, and 3.2-foot sea level rise (SLR) scenarios for the year 2100. Any references to the SLR-XA boundary throughout project documentation assumes the 3.2-foot SLR scenario unless otherwise noted. Areas and assets, including Honoapiilani Highway, within the SLR-XA boundary are considered exposed and potentially vulnerable to SLR. Therefore, the primary purpose of the project is to avoid the SLR-XA where feasible. The FHWA and HDOT will determine feasibility by considering basic design and engineering limitations as described

in the Alternatives Screening Criteria section of the Supplementary NOI Document. Where highway improvements cannot be conducted entirely beyond the SLR-XA, HDOT may seek design solutions to elevate the highway by a height to be determined by technical evaluations conducted as part of this NEPA review.

Although we know that Honoapiilani Highway is vulnerable to flooding and coastal erosion, there may be other reasons to improve road conditions. Agencies and the public are invited to comment on the Purpose and Need. The FHWA and HDOT will finalize the Purpose and Need after the public scoping review period is complete. The Draft EIS will present supporting documentation for the finalized Purpose and Need. Please see the scoping comment period deadline in the **DATES** section of this NOI.

3. Preliminary Description of Project Alternatives

The proposed action is anticipated to include improvements to Honoapiilani Highway for six (6) miles from Papalaua Wayside Park in Ukumehame to the Lahaina Bypass in Launiupoko. Alternatives include the No-Build Alternative and multiple Build Alternatives. The Supplementary NOI Document describes alternatives screening or evaluation criteria, which will be used to filter and prioritize a reasonable number of Build Alternatives to analyze in the Draft EIS. Agencies and the public are invited to comment on the project alternatives and screening criteria. The FHWA and HDOT may modify project alternatives and screening or evaluation criteria based on public scoping input received during the comment period associated with this notice. See below for the range of alternatives currently under consideration.

Build Alternatives

The proposed Build Alternatives are based on alternatives that were proposed in the Maui County 2005 *Pali to Puamana Parkway Master Plan*, which examined possible realignments of Honoapiilani Highway between Ukumehame and Launiupoko. Early scoping meetings and exchanges conducted in the first half of 2022 with Native Hawaiian descendants of Olowalu, Ukumehame, and Lahaina, as well as developers and landowners, and Maui County staff have yielded input critical to refining these alternatives. Adjustments were made with specific consideration for natural resources (water, wetlands, terrain) and the human environment (land use,

ownership, cultural and archaeological resources). Build Alternatives 1 through 4 are presented below. The Supplementary NOI Document contains maps and additional information on the alternatives. For portions of alignments that remain within the SLR-XA boundary, the FHWA and HDOT will conduct additional evaluations to determine the depths of inundation at those locations and appropriate design solutions, such as whether the road should be elevated.

The Supplementary NOI Document also describes other alternatives that were previously considered but have not been retained for consideration in the EIS either because they do not meet the preliminary Purpose and Need or they had been eliminated due to technical challenges, such as drilling a tunnel through the *pali* (cliff) or constructing an ocean causeway.

Build Alternative 1

Build Alternative 1 was adapted from the Maui County Pali to Puamana Parkway 2005 coastal or *makai* concept. A key element of this alternative is to maximize use of the existing Honoapiilani Highway right-of-way (ROW), particularly through Launiupoko and a portion of Olowalu. The Olowalu section of this Alternative was modified to move the Highway further inland near Kapaiki Place neighborhood on Olowalu Village Road (shown on Figure 1) to avoid cultural resources based on recommendations from the community during early scoping meetings. As the alignment proceeds toward Ukumehame Stream, it stays primarily within County and State-owned properties. At Ukumehame Stream, the alignment returns closer to the existing highway to minimize potential impacts to land uses, which may be considered cultural practices, occurring on a property identified as a Land Commission Award (LCA) at the *makai* end of Ukumehame Stream. At the Ukumehame Firing Range, this alternative crosses through the SLR-XA, but avoids a sediment basin, which the U.S. Fish and Wildlife Service's National Wetlands Inventory Mapper (NWI) identifies as a potential wetland area, *mauka* of the existing Honoapiilani Highway. Alternative 1 would avoid approximately 84 percent of the SLR-XA encroachment area on the existing highway. Roughly 0.6 mile (about 3,330 feet) of this alignment would remain inside the SLR-XA.

Build Alternative 2

Build Alternative 2 was adapted from the Maui County Pali to Puamana Parkway 2005 "middle" concept. In

Launiupoko, this alignment would remain close to the existing Honoapiilani Highway. As this alignment crosses Olowalu, it would require the acquisition of private property, including a number of LCA lands in Olowalu. However, the Alternative would avoid the Kapaiki Place residential neighborhood. In Ukumehame, this alignment follows a more *makai* route to maximize use of County and State-owned property like Alternative 1 and stays closer to the existing Honoapiilani Highway, thereby avoiding impacts to the LCA at the *makai* end of Ukumehame Stream. Unlike Alternative 1, this alignment would not avoid the SLR-XA at Ukumehame Stream, because it seeks to keep as close to the existing Honoapiilani Highway as possible. This alignment would remain in the SLR-XA until it reaches the sediment basin below Ukumehame Firing Range. This sediment basin contains an area identified by the U.S. Fish and Wildlife Service's NWI as a potential wetland area.

Alternative 2 traverses the *makai* side of the sediment basin roughly following the *mauka* edge of the SLR-XA. As a result, this alignment does not avoid as much of the SLR-XA as Alternative 1. Alternative 2 would avoid approximately 71 percent of the SLR-XA on the existing highway. Roughly 1.1 miles (about 6,000 feet) of this alignment would remain inside the SLR-XA.

Build Alternative 3

Build Alternative 3 was adapted from the Maui County Pali to Puamana Parkway 2005 "*mauka*" concept. It is identical to Alternative 2, except in Olowalu where the alignment is further inland or *mauka*. At Olowalu, adjustments were made to this alignment to avoid affecting properties with permitted building plans that are near to beginning construction and to be more cohesive with the private subdivision's greenway and existing roadway and utility easements. Preliminary engineering investigations and comments from early scoping suggest that the terrain underlying Alternative 3 may be more variable and challenging than Alternative 2. The alignment would also require acquisition of private property and avoid the Kapaiki Place residential neighborhood. Alternative 3 would avoid approximately 71 percent of the SLR-XA on the existing highway, similar to Alternative 2. Roughly 1.1 miles (about 6,000 feet) of this alignment would remain inside the SLR-XA.

Build Alternative 4

Build Alternative 4 was also adapted from the Maui County Pali to Puamana Parkway 2005 *mauka* concept. The alignment for Alternative 4 was selected to realign the highway as much as possible away from the SLR-XA, without as much consideration for property ownership as other Build Alternatives. The route through Olowalu town that distinguishes this alignment is based on preliminary landowner input provided in 2007. This alignment was further adjusted in 2022 to minimize the creation of remnant parcels by following proposed roads and property boundaries where possible. In doing so, it provides opportunities for multimodal connectivity between the private subdivision's greenway and the realigned highway. In Olowalu, Alternative 4 avoids the Kapaiki Place neighborhood but comes close to the Kipuka Olowalu Cultural Reserve, the site of the Olowalu Petroglyphs. Alternative 4 proposes to span a No Build Archaeological Buffer along Ukumehame Stream with a bridge, to avoid impacts to this archaeological preservation area that was established as part of the Ukumehame Subdivision project, according to a 2005 Final Environmental Assessment.

While other alternatives turn *makai* at Mopua (a locale at the southeastern end of Olowalu), only Alternative 4 continues *mauka* to realign the highway as much as possible away from the SLR-XA. It proceeds toward the Ukumehame Firing Range through private property and passes through the sediment basin before connecting back to the existing highway. Alternative 4 would avoid roughly 92 percent of the SLR-XA on the existing highway, avoiding the SLR-XA the most of all Build Alternatives. Roughly 0.3 mile (about 1,600 feet) of this alignment would remain inside the SLR-XA.

No-Build Alternative

In accordance with the Council on Environmental Quality's regulations implementing NEPA (40 CFR part 1502.14(c)), the EIS will retain the No-Build Alternative for detailed study and serve as a benchmark for comparison with the Build Alternatives. The No-Build Alternative reflects future conditions if the proposed project were not constructed. Soft protections such as nature-based solutions, hard protections such as revetments and seawalls, or a combination of protections and elevating the road are short- to mid-term fixes and would be included in the No-Build Alternative due to the current state of the road and chronic impacts

from coastal hazards. Future conditions would be based on projections of land use and development that are likely to occur 25 years after the project construction. The EIS will provide a comparison of project impacts based on the planning horizon year 2050.

4. Brief Summary of Anticipated Impacts

Given the scope, scale, and complexity of improving the resiliency of a coastal highway, FHWA and HDOT anticipate that the project will likely have significant impacts to the local environment. Agencies, stakeholders, and the public are invited to comment on the expected impacts to be analyzed in the EIS, as well as avoidance, minimization, and mitigation measures. The EIS will evaluate the potential social, economic, and environmental effects resulting from the implementation of the Build Alternatives and the No-Build Alternative.

Additional areas of investigation for this project will include, but not be limited to, consistency with existing plans and land uses, biological resources, cultural resources, archaeological resources, air quality, noise and vibration impacts, social impacts such as shoreline access, land use (residential displacements and local business impacts), recreational resources, visual impacts, traffic impacts, engineering feasibility, project schedule, and ease of implementation. The most sensitive resources requiring evaluation in the project area are likely to be the following:

- *Relocations:* The Build Alternatives may require ROW acquisitions in partially-developed agricultural subdivisions and County-owned lands. The FHWA and HDOT will work closely with any impacted stakeholders to avoid full displacement of a home or business.
- *Historic Properties:* Numerous archaeological, historical, and cultural sites are present in the project study area, including well-known sites such as the Olowalu Petroglyphs and Kipuka Olowalu Cultural Reserve. The EIS will provide a summary discussion of archaeological, historical, and cultural resources. Given the prolific pre-contact settlement in this area, at the request of the native Hawaiian families, the project would avoid LCAs whenever possible to minimize potential impacts to archaeological and cultural resources. Other sensitive resources, and technical reports prepared on these subjects, may be kept confidential and would not be reproduced as part of the public distribution of the EIS.

- *Recreational Resources and section 4(f) of the Department of Transportation Act:* Depending on the alignment, the Build Alternatives may affect the publicly owned Ukumehame Firing Range, a park property protected by section 4(f) of the Department of Transportation Act. The FHWA and HDOT will continue to coordinate with Maui County Department of Parks and Recreation to avoid, minimize and/or mitigate possible impacts to Ukumehame Firing Range.

- *Wetlands and Waters of the U.S.:* According to the U.S. Fish and Wildlife Service NWI Wetlands Mapper, small wetlands may exist in the project study area. Further study is needed to delineate any Waters of the U.S. including wetlands. Additionally, bridge crossings would be needed to carry the highway over Launiupoko, Olowalu, and Ukumehame Streams, and other small streams in the project corridor. As an overall project approach, bridge structures associated with Build Alternatives would either avoid placement of fill within Waters of the U.S. by spanning the stream or conform to regional conditions for the U.S. Army Corps of Engineers (USACE) Clean Water Act (CWA) section 404 Nationwide Permits. In addition, Build Alternatives may require dredging or filling of jurisdictional wetlands or other Waters of the U.S. which would also require a section 404 permit from USACE.

- Important agricultural lands are present throughout the project study area, including Agricultural Lands of Importance to the State of Hawaii (ALISH) and Federally-defined Prime and Unique agricultural lands. Potential impacts to farmlands would be evaluated according to the Federal Farmland Protection Policy Act (FPPA).

- *Environmental Justice (EJ):* In accordance with E.O. 12898, FHWA must identify and address disproportionately high and adverse impacts to low-income and minority EJ populations. The Draft EIS will include information on the location of and project effects on EJ populations, such as the communities of Olowalu and Ukumehame, including the neighborhood of Kapaiki Place, to evaluate the potential for adverse effects. Impacts to EJ communities may include ROW acquisition for a new alignment, increases in noise, or other environmental factors. The FHWA and HDOT will work closely with the community to identify and incorporate measures to avoid adverse effects and if possible, reduce impacts to any disproportionately high and adverse

effects on EJ Population's health or environment.

It should be noted that avoiding impacts on some resources would require trade-offs with impacts to other resources. For example, while none of the alternatives would fully avoid the SLR-*XA*, some would do so more than others. Achieving more avoidance of or adaptation within the SLR-*XA* inundation zone may require more land acquisitions, use of steep and difficult terrain, and/or elevating the roadway. These options would likely increase environmental impacts and overall project costs. Similarly, all alternatives being retained for evaluation in the EIS would affect some LCAs because avoiding most or all LCAs would require a much further *mauka* route with significant increase to environmental impacts and costs or would result in keeping the highway essentially unchanged in its current alignment.

The FHWA and HDOT will produce a Draft and Final Environmental Impact Statement (Draft EIS and Final EIS) and the Record of Decision (ROD). The FHWA and HDOT plan to identify the preferred alternative in the Draft EIS. The Draft EIS will also include measures to avoid, minimize, or mitigate any significant adverse impacts. The NEPA Final EIS and ROD are anticipated to be combined.

Environmental impact analysis will not begin until the public comment period on the NOI has ended. The identification of impacts may be revised due to the consideration of public comments. See the Supplementary NOI Document for a more detailed description of the affected environment. The studies to identify the impacts, as well as the analyses of impacts from the retained alternatives, will be presented in the EIS.

5. Anticipated Permits and Other Authorizations

The FHWA and HDOT anticipate that this Project will require the following Federal, State, and county approvals, permits, and authorizations:

Federal

- USACE CWA section 404
- Department of Transportation Act of 1966, section 4(f) Evaluation
- Federal Emergency Management Agency (FEMA) Floodplain Coordination
- Endangered Species Act, section 7 Consultation
- Farmland Protection Policy Act Farmland Conversion Impact Rating
- Magnuson-Stevens Fishery

Conservation and Management Act, Essential Fish Habitat coordination

- National Historic Preservation Act, section 106 consultation
- Clean Air Act, section 309

State of Hawaii

- Hawaii Revised Statutes (HRS) Chapter 343 EIS
- Coastal Zone Management Act (CZMA), Consistency Determination
- CWA section 401, Water Quality Certification
- CWA section 402, National Pollutant Discharge Elimination System (NPDES) Permit
- HRS Chapter 6E-8, historic preservation review
- Stream Channel Alteration Permit (SCAP)
- Conservation District Use Permit
- Americans with Disabilities Act Accessibility Guidelines
- Community Noise Permit/Community Noise Variance

County of Maui

- Special Management Area (SMA) Permit
- Building and Grading permits

6. Schedule for the Decision-Making Process

The project schedule will be established as part of the requirements of the environmental review process under 23 U.S.C. 139 and will comply with 40 CFR part 1501.10(b)(2), which requires environmental review for a 23 U.S.C. 139 "major project" to be completed within two years (from the date of publication of the NOI to the date of issuance of the Record of Decision [ROD]).

The following is the anticipated project schedule:

- Initiate early scoping and hold Town Hall #1—February 2022;
- Develop preliminary project purpose and need—April 2022;
- Publish Notice of Intent (NOI) and Environmental Impact Statement Preparation Notice (EISPN)—November 2022;
- Scoping Meeting (Town Hall #2)—December 2022;
- Analyze the range of project alternatives—November 2023;
- Publish NEPA/HEPA Draft EIS with the preferred alternative identified—November 2023;
- Public Hearing—December 2023;
- Publish combined NEPA Final EIS and ROD/HEPA Final EIS—June 2024;
- HEPA Final EIS Governor Acceptance—July 2024; and
- Complete permits, licenses, or approvals after the ROD.

7. A Description of the Public Scoping Process

The FHWA and HDOT welcome input on the Purpose and Need of the project; alternatives for consideration; items for further study or analysis; and other aspects of the project to ensure that all potential issues are identified. Regulations implementing NEPA, as well as 23 U.S.C. 139, also call for agency and public involvement in the EIS process. To comply with these regulations, FHWA and HDOT developed a Coordination Plan for Public Outreach and Agency Involvement (Coordination Plan). This plan articulates the roles and responsibilities of those agencies invited to participate as Cooperating or Participating Agencies in the project development and review process.

Consistent with the Coordination Plan, FHWA and HDOT held informal community town hall meetings on February 22 and 24, 2022. In addition, FHWA and HDOT will hold public scoping meetings and a public hearing during the NEPA review. The community will be invited to these meetings through a combination of mailout notices and public notices (such as in the newspaper). Community meetings will be held at times and locations convenient to those that work and live in the corridor. These meetings may be conducted virtually, in-person, or a hybrid of both. Language assistance will be provided upon request and through advice of local community leaders.

To assist in determining the scope of issues to be addressed and identifying the potential for significant issues related to the proposed action, the public will have the opportunity to submit written comments at the public scoping meeting and during the 30-day scoping comment period beginning on the date of this NOI publication. A Draft EIS will be developed following the scoping period and made available for public and agency review and comment prior to the Draft EIS Public Hearing.

Information about public meetings is available on the project website. Please also refer to the **DATES** and **Schedule** for the Decision-Making Process sections of this Notice.

8. Contact Information

Please direct comments or questions concerning this proposed action and the EIS to the FHWA and HDOT contacts as specified in the **FOR FURTHER INFORMATION CONTACT** section at the beginning of this notice.

Authority: 42 U.S.C. 4321 *et seq.*; 23 U.S.C. 139; 23 CFR part 771.

Richelle Takara,

Division Administrator, Federal Highway Administration, Honolulu, Hawaii.

[FR Doc. 2022–25368 Filed 11–21–22; 8:45 am]

BILLING CODE 4910–22–P

DEPARTMENT OF TRANSPORTATION

Federal Highway Administration

Environmental Impact Statement: Contra Costa, Alameda, & San Joaquin Counties, California

AGENCY: Federal Highway Administration (FHWA), Department of Transportation (DOT).

ACTION: Notice of intent.

SUMMARY: The FHWA, on behalf of the California Department of Transportation (Caltrans), is issuing this notice to advise the public that a Draft Environmental Impact Statement (Draft EIS) will be prepared for the proposed State Route (SR) 239 highway project (Project) in Contra Costa, Alameda, and San Joaquin Counties, California.

DATES: This notice will be accompanied by a 62-day public scoping comment period from Friday, November 18, 2022, to January 18, 2023. The deadline for public comments is 5:00 p.m. (PST) on Wednesday, January 18, 2023. Because COVID–19 social distancing advisories are still in effect, no physical public meetings will be held during the public scoping comment period. Instead, Caltrans will hold an online public scoping meeting on Tuesday, December 13, 2022 from 5:30 p.m. to 7:00 p.m. The link to the public scoping meeting will be posted on the project website at www.SR239project.net in advance of the meeting. Additional project information will also be made available on the project website throughout the entire public comment period. The project website at www.SR239project.net can also be accessed through the Caltrans website at <https://dot.ca.gov/caltrans-near-me/district-4/d4-projects/>. Project materials that will be posted on the www.SR239project.net website will include project background, project schedule, frequently asked questions, archival information from prior public outreach presentations, newly developed narrated presentation slides about the SR 239 Project's purpose and need, the alternatives currently being considered, the alternatives previously considered, etc. A poster gallery will also be available that features project alternatives and other key project information.

The website and scoping meeting will enable the public to share thoughts on the project material, the project alternatives under consideration and alternatives previously considered but rejected, and suggest other alternatives. The public can submit formal scoping comments through the www.SR239project.net website via an electronic comment submission form, via email at info@SR239project.net, via the project telephone line at (925) 255–5466, or via postal mail at the contact information listed below. Comments received through these methods will become part of the public record. In addition to email notifications, Caltrans will mail notification postcards via USPS to the public, based on information collected from early public outreach efforts, and to city, county and state officials with jurisdiction in the project area. Postcards provide contact information for requesting information in alternative formats or alternative language translation services.

More information can also be found at the project website at www.SR239project.net or <https://dot.ca.gov/caltrans-near-me/district-4/d4-projects/>.

FOR FURTHER INFORMATION CONTACT:

Caltrans District 4, P.O. Box 23660, MS–8B, Oakland, CA 94623–0660, ATTN: Lily Mu, Environmental Scientist.

SUPPLEMENTARY INFORMATION:

Effective July 1, 2007, the Federal Highway Administration (FHWA) assigned, and the California Department of Transportation (Caltrans) assumed, environmental responsibilities for this project pursuant to 23 U.S.C. 327. Caltrans as the assigned National Environmental Policy Act (NEPA) agency, and in partnership with the Contra Costa Transportation Authority (CCTA) as the project sponsor, will prepare a Draft EIS on a proposal for construction of a new highway, SR 239, in Contra Costa, Alameda, and San Joaquin Counties, California. The project limits extend from SR 4 near Marsh Creek Road in eastern Contra Costa County to Interstate 580 in Alameda County or to Interstate 205 in San Joaquin County. This new route is needed to ultimately improve the transportation network for an area that has few north-south roadway connections between eastern Contra County and the western San Joaquin Valley. The SR 239 Project is particularly important as it would provide relief from increasing commute traffic through the town of Byron, enhance mobility in eastern Contra Costa County, and improve access to the Byron Airport. Caltrans and CCTA are

also considering multimodal alternatives for the State Route 239 Project, such as transit and active transportation improvements. Project objectives include: improving access and mobility between eastern Contra Costa County and western San Joaquin County, supporting inter-regional north-south goods movement operations, reducing regional/non-local traffic through the Town of Byron, improving access to Byron Airport to support planned development and as an emergency logistics hub, providing improvements for regional and sustainable alternative modes of travel, and providing an enhanced evacuation route in the event of major disasters.

Caltrans and CCTA are evaluating the overall State Route 239 corridor at both a Tier I (program) level and a Tier II (project) level. The Tier I programmatic-level study will evaluate and analyze alternatives that cover the entire SR 239 corridor and will consist of a broad and general assessment used to establish and consider the types of environmental impacts that could occur as a result of the ultimate construction and operation of the entire project. Caltrans and CCTA are also evaluating an initial phase of the State 239 Project at a Tier II project-level of evaluation. The Tier II evaluation will consist of a detailed, site-specific analysis that allows for project approval, design and construction of the initial phase.

Currently, the range of alternatives being considered include either taking no action on the proposed new SR 239 (No-Build Alternative) or proceeding with one of two potential build alternatives for the Tier I corridor. Alternative A would be a four-lane highway with an alignment generally east of the Byron Airport that proceeds southward and towards the west of Mountain House that then connects to the I–580/I–205 interchange. Alternative B would be a four-lane highway with an alignment east of the Byron Airport that would become parallel to and west of Byron Highway before joining Byron Road and connecting to I–205 west of Tracy. With respect to Tier II, this initial phase is proposed to be a two-lane facility (one lane in each direction) between State Route 4 near Marsh Creek Road and the Byron Airport. This initial phase would constitute an initial fundable and operable project segment to connect Vasco Road and Byron Highway and would be common to both build alternatives.

The Tier I (program) and Tier II (project) evaluations will be included in a single combined document, a Tier I/ Tier II EIR/EIS, consistent with the requirements of CEQA and NEPA. Later

phases, beyond the initial phase, would require future separate Tier II (project-level) environmental documents before they are programmed for design and construction.

Federal permits and approvals are anticipated from the U.S. Fish and Wildlife Service (USFWS), U.S. Bureau of Reclamation (USBR), U.S. Army Corps of Engineers (USACE), National Marine Fisheries Service (NMFS), and the U.S. Department of the Interior under Section 4(f) of the Department of Transportation Act (1966).

Letters describing the proposed action and soliciting comments will be sent to appropriate Federal, State, Cooperating and Participating Agencies, local agencies, Tribal governments including the Costanoan, Me-Wuk, Miwok, Costanoan Northern Valley Yokut, Pomo, Foothill Yokut Mono, Bay Miwok Ohlone Patwin Plains Miwok, and Bay Miwok Ohlone Delta Yokut tribes, as well as to private organizations and citizens who have previously expressed or are known to have interest in this proposal. The project team anticipates reviewing all public comments received during the public scoping period and circulating a Draft EIS. In addition, a public hearing will be held once the Draft EIS is completed. Public notice will be given of the time and place of the meeting and hearing. The Draft EIS will be available for public and agency review and comment prior to the public hearing to ensure that the full range of issues related to this proposed action are addressed and all significant issues identified, comments, and suggestions are invited from all interested parties. Comments or questions concerning this proposed action and the Draft EIS should be directed to Caltrans at the address provided above.

(Catalog of Federal Domestic Assistance Program Number 20.205, Highway Planning and Construction. The regulations implementing Executive Order 12372 regarding intergovernmental consultation on Federal programs and activities apply to this program.)

Antonio Johnson,

Director, Planning, Environment, and Right of Way, Federal Highway Administration, California Division.

[FR Doc. 2022-25444 Filed 11-21-22; 8:45 am]

BILLING CODE 4910-22-P

DEPARTMENT OF TRANSPORTATION

Federal Railroad Administration

[Docket Number FRA-2008-0028]

Petition for Extension of Waiver of Compliance

Under part 211 of title 49 Code of Federal Regulations (CFR), this document provides the public notice that on October 31, 2022, Riverport Railroad, LLC (RVPR) petitioned the Federal Railroad Administration (FRA) for an extension of a waiver of compliance from certain provisions of the Federal railroad safety regulations contained at 49 CFR part 223 (Safety Glazing Standards—Locomotives, Passenger Cars and Caboose). The relevant FRA Docket Number is FRA-2008-0028.

Specifically, RVPR requests relief from § 223.11(a), *Requirements for Existing Locomotives*, for one locomotive, RVPR 4029, for operations not exceeding 10 miles per hour over a section of track on the former Department of Defense Savanna Army Depot. The installation is located in rural northwestern Illinois, with 80 percent of the adjoining land owned by RVPR and partially under private ownership. In support of its petition, RVPR states that the subject trackage is enclosed and there are no overhead structures or bridges from which objects could be thrown.

A copy of the petition, as well as any written communications concerning the petition, is available for review online at www.regulations.gov.

Interested parties are invited to participate in these proceedings by submitting written views, data, or comments. FRA does not anticipate scheduling a public hearing in connection with these proceedings since the facts do not appear to warrant a hearing. If any interested party desires an opportunity for oral comment and a public hearing, they should notify FRA, in writing, before the end of the comment period and specify the basis for their request.

All communications concerning these proceedings should identify the appropriate docket number and may be submitted at <https://www.regulations.gov>. Follow the online instructions for submitting comments.

Communications received by January 23, 2023 will be considered by FRA before final action is taken. Comments received after that date will be considered if practicable. Anyone can search the electronic form of any written communications and comments received into any of our dockets by the

name of the individual submitting the comment (or signing the document, if submitted on behalf of an association, business, labor union, etc.). Under 5 U.S.C. 553(c), the U.S. Department of Transportation (DOT) solicits comments from the public to better inform its processes. DOT posts these comments, without edit, including any personal information the commenter provides, to www.regulations.gov, as described in the system of records notice (DOT/ALL-14 FDMS), which can be reviewed at <https://www.transportation.gov/privacy>. See also <https://www.regulations.gov/privacy-notice> for the privacy notice of www.regulations.gov.

Issued in Washington, DC.

John Karl Alexy,

Associate Administrator for Railroad Safety, Chief Safety Officer.

[FR Doc. 2022-25322 Filed 11-21-22; 8:45 am]

BILLING CODE 4910-06-P

DEPARTMENT OF TRANSPORTATION

Federal Railroad Administration

[Docket Number FRA-1999-5102]

Petition for Extension of Waiver of Compliance

Under part 211 of title 49 Code of Federal Regulations (CFR), this document provides the public notice that on October 21, 2022, Southeastern Pennsylvania Transportation Authority (SEPTA) petitioned the Federal Railroad Administration (FRA) for an extension of a waiver of compliance from certain provisions of the Federal railroad safety regulations contained at 49 CFR 213.233, *Track inspections*. The relevant FRA Docket Number is FRA-1999-5102.

Specifically, SEPTA requests an extension of its existing waiver for a reduced frequency of the required visual track inspections for FRA Class 3 and 4 track carrying passenger traffic and constructed with continuous welded rail. SEPTA proposes to continue conducting one visual track inspection per week, instead of the two visual inspections per week that are required by § 213.233(c), and to supplement its visual inspections with Track Geometry Measurement System-equipped vehicle inspections over the affected main tracks and sidings four times per year. In support of its petition, SEPTA states that the current inspection program on tracks included in the relief “has continued to successfully monitor track conditions and provide the pertinent information necessary to identify and

correct deteriorating conditions before they become problems.”

A copy of the petition, as well as any written communications concerning the petition, is available for review online at www.regulations.gov.

Interested parties are invited to participate in these proceedings by submitting written views, data, or comments. FRA does not anticipate scheduling a public hearing in connection with these proceedings since the facts do not appear to warrant a hearing. If any interested party desires an opportunity for oral comment and a public hearing, they should notify FRA, in writing, before the end of the comment period and specify the basis for their request.

All communications concerning these proceedings should identify the appropriate docket number and may be submitted at <http://www.regulations.gov>. Follow the online instructions for submitting comments.

Communications received by January 23, 2023 will be considered by FRA before final action is taken. Comments received after that date will be considered if practicable.

Anyone can search the electronic form of any written communications and comments received into any of our dockets by the name of the individual submitting the comment (or signing the document, if submitted on behalf of an association, business, labor union, etc.). Under 5 U.S.C. 553(c), the U.S. Department of Transportation (DOT) solicits comments from the public to better inform its processes. DOT posts these comments, without edit, including any personal information the commenter provides, to www.regulations.gov, as described in the system of records notice (DOT/ALL-14 FDMS), which can be reviewed at <https://www.transportation.gov/privacy>. See also <https://www.regulations.gov/privacy-notice> for the privacy notice of www.regulations.gov.

Issued in Washington, DC.

John Karl Alexy,
Associate Administrator for Railroad Safety
Chief Safety Officer.

[FR Doc. 2022-25321 Filed 11-21-22; 8:45 am]

BILLING CODE 4910-06-P

DEPARTMENT OF TRANSPORTATION

Federal Railroad Administration

[Docket Number FRA-2018-0006]

Petition for Extension of Waiver of Compliance

Under part 211 of title 49 Code of Federal Regulations (CFR), this

document provides the public notice that on October 18, 2022, Northern Plains Railroad (NPR) petitioned the Federal Railroad Administration (FRA) for an extension of a waiver of compliance from certain provisions of the Federal railroad safety regulations contained at 49 CFR 229.47, *Emergency brake valve*. The relevant FRA Docket Number is FRA-2018-0006.

Specifically, NPR requests to extend its existing relief from the requirement that an emergency brake pipe valve be installed adjacent to the rear door of a locomotive for five EMD SD60F locomotives (Numbers 5513, 5517, 5518, 5525, and 5535). The five locomotives are of the same car body type and are not equipped with an emergency brake valve at the rear exit door. Each of the units have rear walkways and switch style steps, thus allowing the engineer to see the person riding on the back and are equipped with radio communication. These units will be used in road service and will be paired together. In support of its request, NPR states that it has “no history of vandalism.”

A copy of the petition, as well as any written communications concerning the petition, is available for review online at www.regulations.gov.

Interested parties are invited to participate in these proceedings by submitting written views, data, or comments. FRA does not anticipate scheduling a public hearing in connection with these proceedings since the facts do not appear to warrant a hearing. If any interested party desires an opportunity for oral comment and a public hearing, they should notify FRA, in writing, before the end of the comment period and specify the basis for their request.

All communications concerning these proceedings should identify the appropriate docket number and may be submitted at <http://www.regulations.gov>. Follow the online instructions for submitting comments.

Communications received by January 23, 2023 will be considered by FRA before final action is taken. Comments received after that date will be considered if practicable. Anyone can search the electronic form of any written communications and comments received into any of our dockets by the name of the individual submitting the comment (or signing the document, if submitted on behalf of an association, business, labor union, etc.). Under 5 U.S.C. 553(c), the U.S. Department of Transportation (DOT) solicits comments from the public to better inform its processes. DOT posts these comments, without edit, including any personal

information the commenter provides, to www.regulations.gov, as described in the system of records notice (DOT/ALL-14 FDMS), which can be reviewed at <https://www.transportation.gov/privacy>. See also <https://www.regulations.gov/privacy-notice> for the privacy notice of www.regulations.gov.

Issued in Washington, DC.

John Karl Alexy,

Associate Administrator for Railroad Safety,
Chief Safety Officer.

[FR Doc. 2022-25323 Filed 11-21-22; 8:45 am]

BILLING CODE 4910-06-P

DEPARTMENT OF TRANSPORTATION

Federal Transit Administration

Fiscal Year (FY) 2023 Competitive Funding Opportunity: Transit Standards Development

AGENCY: Federal Transit Administration (FTA), Department of Transportation (DOT).

ACTION: Notice of funding opportunity (NOFO).

SUMMARY: The Federal Transit Administration (FTA) announces the opportunity to apply for up to \$3,000,000 under the Technical Assistance and Workforce Development Program for proposals to develop voluntary standards and standards-related best practices, guidance, and tools in safety, and other areas that improve public transportation by directly engaging and working with transit stakeholders.

DATES: Complete proposals must be submitted electronically through the [GRANTS.GOV](https://www.grants.gov) “APPLY” function by 11:59 p.m. eastern time on January 23, 2023.

Prospective applicants should initiate the process by registering on the [GRANTS.GOV](https://www.grants.gov) website promptly to ensure completion of the application process before the submission deadline. Instructions for applying can be found on FTA’s website at <http://www.transit.dot.gov/howtoapply> and in the “FIND” module of [GRANTS.GOV](https://www.grants.gov). The funding opportunity ID is FTA-2023-004-TRI. Mail and fax submissions will not be accepted.

FOR FURTHER INFORMATION CONTACT: Raj Wagley, FTA Office of Research, Demonstration, and Innovation, phone: (202) 366-5386, or email: raj.wagley@dot.gov.

SUPPLEMENTARY INFORMATION:

Table of Contents

A. Program Description

- B. Federal Award Information
- C. Eligibility Information
- D. Application and Submission Information
- E. Application Review Information
- F. Federal Award Administration Information
- G. Federal Awarding Agency Contacts
- H. Other Information

A. Program Description

Under FTA's Technical Assistance and Workforce Development Program (49 U.S.C. 5314), FTA may make grants, or enter into contracts or cooperative agreements, for the development of standards, best practices, guidance, and tools for the public transportation industry. This Notice of Funding Opportunity (NOFO) (Federal Assistance Listing: 20.531) is issued under this authority.

Transit standards are essential tools for public transportation agencies to consistently and efficiently deploy and operate their transit systems. Transit industry standards promote operating transit vehicles safely, implementing innovative mobility models consistently and efficiently, addressing rail/rail crossing safety, increasing resiliency, providing better information to travelers, ensuring data integration, supporting battery electric bus and charging systems interoperability, improving cybersecurity, implementing integrated fare payment systems, assisting in emergency response communication, improving worker safety, and enhancing performance in many other areas. Additionally, standards provide value to manufacturers of public transit products and services and to the transit agencies that purchase those products and services by ensuring they meet specific performance criteria and address interoperability and safety.

Previous standards projects assessed gaps in standards, identified areas where standards were needed, and provided support to develop voluntary standards for bus and rail safety, zero emission vehicles and charging infrastructure, facility maintenance, training, operator safety, crashworthiness, and other important topics. Along with the innovations and emerging technologies, the previous work provides a foundation and need for exploring new standards or modification of existing standards. The main goal of this program is to identify industry needs for standards and develop voluntary standards in one or more areas.

The selected recipient will perform an industry standards assessment and develop a priority list of standards that require immediate action. Upon direction from FTA, the recipient will

develop or modify voluntary standards, best practices, guidance, and tools to help public transit agencies adopt those standards. Standards development must directly engage a broad group of transit stakeholders, including Federal, State, local, National, public, nonprofit, academic, and private sector representatives. Eligible standards areas can include, but are not limited to, bus and rail safety, mobility, fare collection, intelligent transportation systems, accessibility, equitable service standards, procurement, security, resiliency, asset management to maintain a state of good repair, operations, maintenance, zero emission vehicles, charging systems, maintenance facilities, bus workstations, traveler information, interoperable data standards, vehicle propulsion, emergency response communications, and vehicle electronics. FTA will create an internal FTA Standards Working Group (SWG), which will work with the selected applicant, its industry partners, working groups, and standards development organizations in the assessment, review, prioritization, and selection of transit standards to be developed or modified. One applicant will be competitively selected based on the criteria outlined in this NOFO.

Key tasks for this NOFO include:

- *Standards Assessment:* Collect and analyze industry data to assess industry needs for areas of new standards development or modification of existing standards. This can include industry scans, listening sessions or surveys, review of current transit literature, and review of prior FTA standards development reports which can be found at: <https://www.transit.dot.gov/research-innovation/fta-reports-and-publications>;

- *Propose Areas for Standards Development:* Based on the results of the industry scan, identify potential areas for new standards development or modification of existing standards;

- *Vet Proposed Standards Areas:* Gather feedback from a broad set of public transit stakeholders on proposed standards areas—ensure there is alignment of industry standards needs and solutions with FTA priorities;

- *Prioritize Standards with FTA:* Engage with FTA's SWG in the prioritization and selection of standards. For all proposed standards, the recipient should ensure each proposed standards area has expected outcomes and impacts for how the standard will improve public transportation. FTA's SWG will then conduct a gate review, which involves FTA reviewing and approving proposed standards activities. Proposed standards activities may include the

recipient: (1) presenting the results of industry scans and industry feedback to FTA; (2) noting the value/need for certain standards or standards related documents/tools; (3) recommending ways to measure the utility of a proposed action(s); and (4) any other activity that provides FTA with enough information to approve and prioritize the work of this program. FTA's gate review will assign priorities, review expected outcomes, provide feedback to the applicant, and approve the proposed standards for development.

- *Develop Standards and Implementation Resources:* Collaborate with transit stakeholders, FTA SWG, and Standards Development Organizations (SDOs) to develop voluntary standards, guidance, best practice documents and tools following gate approval by FTA.

Applicants must clearly describe in the application how they will accomplish the proposed key tasks. Additionally, applicants must describe how they will work with transit industry stakeholders, industry working groups and standards development organizations—including FTA and its standards working group—in assessing and developing standards, best practices, guidance, and tools that improve public transportation.

FTA's role will include the review and approval of proposed standards through its internal FTA Standards Working Group; development of project reports and review of documents; and participation in key decisions, including if there is a need to redirect and reprioritize project activities, goals, and deliverables.

B. Federal Award Information

This notice makes available up to \$3,000,000 of FTA Technical Assistance and Workforce Development Program (49 U.S.C. 5314) funds for a cooperative agreement to support the assessment of need and development of voluntary public transportation standards as well as appropriate best practices, guidance, and tools to implement those standards to provide public transportation service effectively and efficiently.

FTA may award additional funds if they are made available to the program prior to the announcement of the project selection. If additional funds are made available during project execution and can be added to the selected project, FTA would require an amendment to the existing award. Only proposals from eligible applicants for eligible activities will be considered for funding. FTA may cap the amount a recipient may receive as part of the selection process.

Pre-award authority is subject to FTA approval and is only available for costs incurred after the announcement of project selections on FTA's website.

Projects under this competition are for standards development efforts and, as such, FTA Circular 6100.1E (available at <https://www.fta.dot.gov/regulations-and-guidance/fta-circulars/research-technical-assistance-and-training-program>) will apply in administering the program.

An applicant whose proposal is selected for funding will receive a cooperative agreement with FTA, to be administered according to Circular 6100.1E, and as set forth in 31 U.S.C. 6305. FTA will have substantial involvement in the administration of the cooperative agreement.

C. Eligibility Information

1. Eligible Applicants

Eligible applicants under this notice include the following:

(1) Providers of public transportation, including public transportation agencies, State or local government DOTs, and federally recognized Indian tribes;

(2) Private for-profit and not-for-profit organizations, or consultants;

(3) State, city, or local government entities, including multi-jurisdictional partnerships, and organizations such as Metropolitan Planning Organizations;

(4) Other organizations, including research consortia, not-for-profit industry organizations, and institutions of higher education, including large research universities, particularly those with Minority Serving Institution status; or

(5) Standard Development Organizations (SDOs).

On the application form, eligible applicants are strongly encouraged to identify one or more project partners with a substantial interest and involvement in the project activities or objectives to participate in the implementation of the project. If an application that involves such a partnership is selected for funding, the competitive selection process will be deemed to satisfy the requirement for a competitive procurement under 49 U.S.C. 5325(a) for the named entities. Applicants are advised that any changes to the proposed partnership after the award will require FTA written approval and must be consistent with the scope of the approved project. Post-award changes usually will be subject to ordinary procurement standards.

The applicant must be able to carry out the proposed agreement and procurements, if needed, with project

partners in compliance with all applicable Federal, State, and local laws.

To be considered eligible, applicants must be able to demonstrate the requisite legal, financial, and technical capabilities to receive and administer Federal funds under this program.

2. Cost Sharing or Matching

The eligible Federal share for the cooperative agreement that will be awarded for this program is 100 percent. No non-Federal cost sharing is required; however, applicants may offer a non-Federal share of costs. Applications that offer a non-Federal share of costs will be given additional consideration. For guidance related to cost sharing, please see FTA Circular 6100.1E.

3. Eligible Projects

This notice solicits applications to support the assessment of need and development of voluntary public transportation standards as well as appropriate best practices, guidance, and tools to implement those standards to provide public transportation service more effectively and efficiently. The eligible areas for standards development include, but are not limited to, bus and rail safety, fare collection, intelligent transportation systems, accessibility, equitable service standards, procurement, security, resiliency, asset management to maintaining a state of good repair, operations, maintenance, zero emission vehicles, charging systems, maintenance facilities, bus workstations, traveler information, interoperable data standards, vehicle propulsion, emergency response communications, and vehicle electronics. One critical component of the project is to engage with FTA's own Standards Working Group (SWG) in the decision and prioritization of standard development activities.

Eligible activities are all activities noted in the required tasks and any other appropriate actions that lead to development of transit standards, best practices, guidance, and tools, including but not limited to:

- industry scans, listening sessions or surveys, case studies, and data collection on industry needs;
- new and emerging technology specifications and standards;
- identification of innovations to provide more effective and efficient systems using public-private partnerships with non-traditional transportation providers;
- industry literature reviews on transit needs and gaps, domestic and international;

• surveys on systems and products in other industries that could be applicable to public transit systems;

- data analytics;
- establishing various use cases for emerging and innovation deployment;
- defining system requirements;
- modeling and simulation;
- development, validation, and verification of the data and specification; and
- development of new standards and standards documents for transit innovations and solutions to share with the transit industry, including transit bus manufacturers.

Standards or standards-related best practices, guidance, and tools developed or modified will be disseminated on a standard development organization website, FTA website, or through public organizations for transit agencies and transit industry for their use. Standards or standards-related best practices, guidance, and tools developed under this program must not negatively impact interoperability, integrability, efficiency, effectiveness, and safety of the transit systems, process, and devices. Further, the recipient should consider how this standard development effort could support the development or use of additional standards, specifications, or protocols as appropriate.

D. Application and Submission Information

1. Address To Request Application

Applications must be accessed and submitted electronically through *GRANTS.GOV*. General information for submitting applications through *GRANTS.GOV* can be found at www.transit.dot.gov/howtoapply. A complete proposal submission consists of two forms and their supporting attachments. The Forms are: (1) an SF-424 "Application for Federal Assistance," and (2) the supplemental form for the Transit Standards Development NOFO. Both forms are downloadable from *GRANTS.GOV* or the FTA website at <https://www.transit.dot.gov/research-innovation/standards-development-program>.

2. Content and Form of Application Submission

a. Proposal Submission

A complete proposal submission consists of the two forms (SF-424 and the supplemental form) and their supporting documents. The supporting documents and attachments shall provide a detailed project approach and proposed scope of work.

The supplemental form and supporting documents must be added to the “Attachments” section of the SF–424. The application must include responses to all sections of the SF–424 Application for Federal Assistance and the supplemental form, unless indicated as optional. The information on the supplemental form will be used to determine applicant and project eligibility for the program, and to evaluate the proposal against the selection criteria described in section E of this notice.

FTA will accept only one supplemental form per SF–424 submission. Applicants may attach additional supporting information to the SF–424 submission, including but not limited to a detailed project approach, the project background, a proposed scope of work and major tasks, a proposed timeline, proposed project budgets, technical information and approach, visual aids, excerpts from relevant planning documents, letters of support, or project narratives. Any supporting documentation must be described and referenced by file name in the appropriate response section of the supplemental form, or it may not be reviewed.

Information such as applicant name, Federal amount requested, and local match amount (if match is being proposed), may be requested on both the SF–424 and supplemental form. Applicants must fill in all fields unless stated otherwise on the forms. If information is copied into the supplemental form from another source, applicants should verify that pasted text is fully captured on the supplemental form and has not been truncated by the character limits built into the form. Applicants should use both the “Check Package for Errors” and the “Validate Form” validation buttons on both forms to check all required fields on the forms and ensure that the Federal and local amounts specified are consistent.

b. Application Content

The SF–424 Application for Federal Assistance and the supplemental form will prompt applicants for the required information, including:

1. Applicant name.
2. Unique Entity Identifier (UEI) in <https://www.sam.gov>. The Federal government stopped using the Data Universal Numbering System (DUNS) number to identify entities as of April 4, 2022.
3. Key contact information (including name, address, email address, and phone).
4. Congressional district(s) where project will take place.

5. Project information (including title, and an executive summary).

6. Project description (including attachments if necessary) of how it will: (a) collect and analyze industry data to assess industry needs for the development of standards; (b) align industry standards needs and solutions with FTA priorities; (c) coordinate with industry stakeholders and working groups; (d) engage with FTA’s SWG in the prioritization and selection of standards for short-term and long-term development; and in a potential subsequent phase to (e) collaborate and facilitate with Standard Development Organizations (SDOs) to develop standards, best practices guidance and tools in the short term.

7. A detailed history of current efforts to establish public transportation standards.

8. Information on any project partners, their role, and anticipated contributions.

9. A description of the technical, legal, and financial capacity of the applicant, its key personnel, and any partners.

10. A detailed project budget, specifying Federal and local share when applicable.

11. A detailed project timeline, including key milestones and interim deliverables.

Please refer to section E.1 for additional guidance on information applicants should provide. Applicants may also attach additional supporting information and other materials or information relevant to transit standards development such as letters of support from key stakeholders.

3. Unique Entity Identifier and System for Award Management (SAM)

Each applicant is required to: (1) be registered in SAM before submitting an application; (2) provide a valid unique entity identifier in its application; and (3) maintain an active SAM registration with current information at all times during which the applicant has an active Federal award or an application or plan under consideration by FTA. FTA may not make an award until the applicant has complied with all applicable unique entity identifier and SAM requirements. If an applicant has not fully complied with the requirements by the time FTA is ready to make an award, FTA may determine that the applicant is not qualified to receive an award and use that determination as a basis for making a Federal award to another applicant. These requirements do not apply if the applicant has an exception approved by FTA or the U.S. Office of Management

and Budget under 2 CFR 25.110(c) or (d). SAM registration takes approximately 3–5 business days, but FTA recommends allowing ample time, up to several weeks, for completion of all steps. For additional information on obtaining a unique entity identifier, please visit <https://www.sam.gov>.

4. Submission Dates and Times

Project proposals must be submitted electronically through *GRANTS.GOV* by 11:59 p.m. Eastern time on January 23, 2023. *GRANTS.GOV* attaches a time stamp to each application at the time of submission. Proposals submitted after the deadline will only be considered under extraordinary circumstances not under the applicant’s control. Mail and fax submissions will not be accepted.

FTA urges applicants to submit applications at least 72 hours prior to the due date to allow time to receive the validation messages and to correct any problems that may have caused a rejection notification. *GRANTS.GOV* scheduled maintenance and outage times are announced on the *GRANTS.GOV* website. Deadlines will not be extended due to scheduled website maintenance. Within 48 hours after submitting an electronic application, the applicant should receive an email message from *GRANTS.GOV* with confirmation of successful transmission to *GRANTS.GOV*. If a notice of failed validation or incomplete materials is received, the applicant must address the reason for the failed validation, as described in the email notice, and resubmit before the submission deadline. If making a resubmission for any reason, include all original attachments regardless of which attachments were updated and check the box on the supplemental form indicating this is a resubmission.

Applicants are encouraged to begin the process of registration on the *GRANTS.GOV* site well in advance of the submission deadline. Registration is a multi-step process, which may take several weeks to complete before an application can be submitted. Registered applicants may still be required to take steps to keep their registration up to date before submissions can be made successfully: (1) registration in SAM is renewed annually, and (2) persons making submissions on behalf of the Authorized Organization Representative (AOR) must be authorized in *GRANTS.GOV* by the AOR to make submission.

5. Funding Restrictions

Funds available under this NOFO cannot be used to reimburse applicants

for otherwise eligible expenses incurred prior to FTA issuing pre-award authority for the selected applicant.

Refer to section C.3., Eligible Projects, for information on activities that are allowable. Allowable direct and indirect expenses must be consistent with the Governmentwide Uniform Administrative Requirements and Cost Principles (2 CFR part 200) and FTA Circular 5010.1E.

6. Other Submission Requirements

Applicants are encouraged to identify scaled funding options in case funding is not available to fund the program at the full requested amount. If an applicant indicates that a project is scalable, the applicant must provide an appropriate minimum funding amount that will fund an eligible project that achieves the objectives of the program and meets all relevant program requirements. The applicant must provide a clear explanation of how the project budget would be affected by a reduced award. FTA may award a lesser amount regardless of whether a scalable option is provided.

All applications must be submitted via the *GRANTS.GOV* website. FTA does not accept applications on paper, by fax machine, email, or other means. For information on application submission requirements, please see section D.1., Address to Request Application.

E. Application Review Information

1. Criteria

Applications will be evaluated on the responses provided in the supplemental form and the attached project summary. Additional information may be provided to support the responses. All additional documentation, including the file names, must be directly referenced on the supplemental form. Applicants must complete the supplemental form and the project attachments.

FTA will evaluate proposals based on the criteria described in this notice.

a. Knowledge of Standards and Standards Development

Applications should provide evidence of applicant's experience developing and disseminating industry standards, particularly for the public transit industry. The proposal should detail the applicant's knowledge of general transit industry standards, general experience and knowledge of transit standards development, including awareness of potential barriers or challenges to standard development and application.

b. Knowledge of Subject Areas, Emerging Needs, and Demands in Transit

Applications should clearly demonstrate applicants' knowledge in a wide range of topics and areas in transit. This may include understanding of industry safety, mobility, and operation needs; accessibility and usability of systems to comply with the Americans with Disabilities Act and Title VI of the Civil Rights Act; process improvement in training, maintenance, and procurement; or work experience or familiarity of new and emerging technologies such as low and no emission vehicles, systems, and devices, including battery electric, fuel cell technologies and automation.

c. Key Personnel Experience and Organizational Capacity

Applications should note the individuals who will be involved in the project and how the applicant will ensure they will have enough time and expertise to carry out project objectives to assess data, coordinate with stakeholders, and develop standards in the program duration of four years. Additionally, applicants should discuss proposed personnel's successful completion of similar or relevant projects, case studies, references, etc.

d. Project Approach

Applications will be evaluated on an overall project approach, including proposed workplan tasks, schedule, and interim deliverables. In assessing whether the proposed implementation plans are reasonable and complete, FTA will review the proposed project work plan, including all necessary milestones and the overall project timeline. Applicants must demonstrate their ability to enter into a cooperative agreement in FTA's Transit Award Management System (TrAMS) and begin project activities within 45 days if selected for award. FTA uses the TrAMS system for cooperative agreement awards.

e. Technical, Legal, and Financial Capacity

The applicant must demonstrate the financial and organizational capacity and managerial experience to successfully oversee and implement this project. FTA may review relevant oversight assessments and records to determine whether there are any outstanding legal, technical, or financial issues with the applicant that would affect the outcome of the proposed project. Applicants with outstanding legal, technical, or financial compliance

issues from an FTA compliance review or Federal Transit grant-related Single Audit finding must explain how corrective actions will mitigate negative impacts on the proposed project.

For applications that include named project partners, FTA will also consider the technical, legal, and financial capacity of the proposed partners.

2. Review and Selection Process

The competitive application review process consists of an initial screen for eligibility followed by a two-phase review process: a technical review and a senior leadership review. An FTA technical evaluation committee will evaluate proposals based on the published evaluation criteria and a rating guidance specific to this NOFO. Members of the technical evaluation committee may request additional information from applicants, if necessary. The second phase is a senior leadership review. Based on the review of the technical evaluation committee, the FTA Administrator will determine the final selection for project funding.

3. Performance and Integrity

Prior to making an award, FTA is required to review and consider any information about the applicant that is in the Federal Awardee Performance and Integrity Information System (FAPIS) accessible through UEI (SAM). An applicant may review and comment on any information about itself that a Federal awarding agency previously entered. FTA will consider any comments by the applicant, in addition to the other information in the designated integrity and performance system, in making a judgment about the applicant's integrity, business ethics, and record of performance under Federal awards when completing the review of risk posed by applicants as described in the Office of Management and Budget's Uniform Requirements for Federal Awards (2 CFR 200.206).

F. Federal Award Administration Information

1. Federal Award Notices

FTA will announce the final applicant selection on the FTA website. Due to funding limitations, the applicant selected for funding may receive less than the amount originally requested. In this case the applicant must be able to demonstrate that the proposed project is still viable and can be completed with the amount awarded.

2. Administrative and National Policy Requirements

a. Pre-Award Authority

At the time the project selection is announced, FTA may extend pre-award authority for the selected project. There is no blanket pre-award authority for the project before announcement. FTA will issue specific guidance to the recipient regarding pre-award authority at the time of selection. FTA does not provide pre-award authority for competitive funds until a project is selected, and even then, there are Federal requirements that must be met before costs are incurred. For more information about FTA's policy on pre-award authority, please see the most recent Apportionments, Allocations and Program Information Notice at 87 FR 25362, 25386.

b. Cooperative Agreement Requirements

If selected, the awardee will apply for a cooperative agreement through FTA's Transit Award Management System (TrAMS). The successful applicant must be prepared to submit a complete statement of work and application in TrAMS and begin project activities within 45 days of notification of award. All recipients must follow the requirements of FTA Circular 6100.1E. Technical assistance regarding these requirements is available from FTA.

c. Standard Assurances

If an applicant receives an award, the applicant must assure that it will comply with all applicable Federal statutes, regulations, executive orders, directives, FTA circulars, and other Federal administrative requirements in carrying out any project supported by the FTA award. The applicant acknowledges that it will be under a continuing obligation to comply with the terms and conditions of the agreement issued for its project with FTA. The applicant understands that Federal laws, regulations, policies, and administrative practices might be modified from time to time and may affect the implementation of the project. The most recent Federal requirements will apply to the project unless FTA issues a written determination otherwise. The applicant must submit the most recent FTA Certifications and Assurances before receiving an award if it does not have current certifications on file.

d. Data Access and Data Sharing

Recipients, including a recipient that is an institution of higher education, will be subject to the restriction on publishing subject data contained in

section 18(b) of the latest version of FTA's master agreement available on FTA's website at <https://www.transit.dot.gov/funding/grantee-resources/sample-fta-agreements/fta-grant-agreements>. A recipient must receive written approval from FTA prior to publishing or presenting subject data in any form. FTA must approve the standards, best practices, guidance, or tools developed under this NOFO before that information can be published. A recipient should consult with its FTA Program Manager prior to accepting an award to discuss any plan for external communications about the project. FTA seeks to improve public transportation for America's communities by sharing project data and information collected or developed through its research with the public. This allows research organizations, transit agencies, and other stakeholders to learn from and expand upon the insights developed from FTA-funded research. Any standards, guidance, tools, or software developed as a part of this solicitation will be evaluated by FTA for the potential to be shared for use by public transportation agencies and others.

3. Reporting

Post-award reporting requirements include the electronic submission of Federal Financial Reports and Milestone Progress Reports in FTA's electronic grants management system.

Applicants should include any goals, targets, and indicators referenced in their application in the Executive Summary of the TrAMS application.

As part of completing the annual certifications and assurances required of FTA grant recipients, a successful applicant must report on the suspension or debarment status of itself and its principals. If the award recipient's active grants, cooperative agreements, and procurement contracts from all Federal awarding agencies exceeds \$10,000,000 for any period of time during the period of performance of an award made pursuant to this Notice, the recipient must comply with the Recipient Integrity and Performance Matters reporting requirements described in appendix XII to 2 CFR part 200.

G. Federal Awarding Agency Contacts

For further information concerning this notice, please contact Raj Wagley, in the FTA Office of Infrastructure, Safety and Asset Innovation, by email at raj.wagley@dot.gov. A TDD is available for individuals who are deaf or hard of hearing at 800-877-8339. In addition, FTA will post answers to questions and requests for clarifications on FTA's

website at <https://www.transit.dot.gov/research-innovation/standards-development-program>. To ensure applicants receive accurate information about eligibility or the program, applicants are encouraged to contact FTA directly with questions, rather than through intermediaries or third parties. FTA staff may also conduct briefings on the competitive applications selection and award process upon request.

For issues with *GRANTS.GOV*, please contact *GRANTS.GOV* by phone at 1-800-518-4726 or by email at support@grants.gov.

H. Other Information

This program is not subject to Executive Order 12372, "Intergovernmental Review of Federal Programs."

Nuria I. Fernandez,
Administrator.

[FR Doc. 2022-25408 Filed 11-21-22; 8:45 am]

BILLING CODE 4910-57-P

DEPARTMENT OF TRANSPORTATION

Maritime Administration

U.S. Merchant Marine Academy Board of Visitors; Public Meeting

AGENCY: Maritime Administration (MARAD), Department of Transportation (DOT).

ACTION: Notice of public meeting.

SUMMARY: MARAD announces a meeting of the U.S. Merchant Marine Academy (USMMA) Board of Visitors (BOV).

DATES: December 14, 2022, from 9 a.m. to 11 a.m. EST.

Requests to submit written materials to be reviewed during the meeting must be received no later than December 2, 2022. Requests for accommodations for a disability must be received by December 7, 2022. USMMA will post virtual meeting access details no later than December 9, 2022, via the Academy website and social media channels.

ADDRESSES: The meeting will be held through a virtual forum. Virtual meeting access information will be available on the USMMA BOV web page no later than December 9, 2022. General information about the committee is available on the USMMA BOV web page at <https://www.usmma.edu/about/leadership/board-visitors>.

FOR FURTHER INFORMATION CONTACT: The BOV's Designated Federal Officer and Point of Contact, Mary Grice, 202-366-4264 or mary.grice@dot.gov.

SUPPLEMENTARY INFORMATION:

I. Background

The USMMA BOV is a Federal Advisory Committee originally established as a Congressional Board by section 51312 of title 46, United States Code “to provide independent advice and recommendations on matters relating to the United States Merchant Marine Academy.” The Board was originally chartered under the Federal Advisory Committee Act (FACA) on October 24, 2017.

II. Agenda

The meeting agenda will cover, *but is not limited to*, the following proposed topics:

1. Board maintenance items (elections, minutes, reports, etc.);
2. Update on Sea Year and EMBARC programs;
3. Update on the six priorities from the USMMA Strategic Plan (including infrastructure and modernization progress, Sexual Assault Prevention and Response program status);
4. Update on the Class of 2026; and
5. Update on the state of the Regiment of Midshipmen.

III. Public Participation

This meeting is open to the public and will be held through a virtual forum. DOT and MARAD are committed to providing equal access to this meeting for all participants. If you need alternative formats or services because of a disability, such as sign language, interpretation, or other ancillary aids, please contact the person listed in the **FOR FURTHER INFORMATION CONTACT** section.

Any member of the public is permitted to file a written statement with the BOV. Written statements should be sent to the Designated Federal Officer listed in the **FOR FURTHER**

INFORMATION CONTACT section no later than December 2, 2022.

Only written statements will be considered by the BOV; no member of the public will be allowed to present questions or speak during the meeting unless requested to do so by a member of the Board.

The meeting notice must be placed in the **Federal Register** no later than 15 days prior to the scheduled date of the meeting, as required by 41 CFR part 102–3.150.

(Authority: 46 U.S.C. 51312; 5 U.S.C. 552b; 5 U.S.C. App. 2; 41 CFR parts 102–3.140 through 102–3.165.)

By order of the Maritime Administrator.

T. Mitchell Hudson, Jr.,

Secretary, Maritime Administration.

[FR Doc. 2022–25440 Filed 11–21–22; 8:45 am]

BILLING CODE 4910–81–P

DEPARTMENT OF TRANSPORTATION

Pipeline and Hazardous Materials Safety Administration

Hazardous Materials: Notice of Applications for Special Permits

AGENCY: Pipeline and Hazardous Materials Safety Administration (PHMSA), DOT.

ACTION: List of applications for modification of special permits.

SUMMARY: In accordance with the procedures governing the application for, and the processing of, special permits from the Department of Transportation’s Hazardous Material Regulations, notice is hereby given that the Office of Hazardous Materials Safety has received the application described herein.

DATES: Comments must be received on or before December 7, 2022.

ADDRESSES: Record Center, Pipeline and Hazardous Materials Safety Administration, U.S. Department of Transportation, Washington, DC 20590.

Comments should refer to the application number and be submitted in triplicate. If confirmation of receipt of comments is desired, include a self-addressed stamped postcard showing the special permit number.

FOR FURTHER INFORMATION CONTACT:

Donald Burger, Chief, Office of Hazardous Materials Safety General Approvals and Permits Branch, Pipeline and Hazardous Materials Safety Administration, U.S. Department of Transportation, East Building, PHH–13, 1200 New Jersey Avenue Southeast, Washington, DC 20590–0001, (202) 366–4535.

SUPPLEMENTARY INFORMATION: Each mode of transportation for which a particular special permit is requested is indicated by a number in the “Nature of Application” portion of the table below as follows: 1—Motor vehicle, 2—Rail freight, 3—Cargo vessel, 4—Cargo aircraft only, 5—Passenger-carrying aircraft.

Copies of the applications are available for inspection in the Records Center, East Building, PHH–13, 1200 New Jersey Avenue Southeast, Washington, DC or at <http://regulations.gov>.

This notice of receipt of applications for special permit is published in accordance with part 107 of the Federal hazardous materials transportation law (49 U.S.C. 5117(b); 49 CFR 1.53(b)).

Issued in Washington, DC, on November 4, 2022.

Donald P. Burger,

Chief, General Approvals and Permits Branch.

Application No.	Applicant	Regulation(s) affected	Nature of the special permits thereof
Special Permits Data			
20333–M	Antonov, dp	172.101(j), 172.203(a), 172.301(c), 173.27(b)(2), 175.30(a)(1).	To modify the special permit to authorize an additional hazardous material and waive part of 49 CFR 107.109(a)(3). (mode 4)
20906–M	Nouryon Functional Chemicals LLC.	173.28(b)(2), 173.181	To modify the special permit to authorize an additional packaging. (modes 1, 2, 3)
21012–M	Linde Gas & Equipment Inc	172.203(a), 180.209, 172.301(c).	To modify the special permit to authorize additional hazardous materials. (modes 1, 2, 3, 4, 5)

DEPARTMENT OF TRANSPORTATION**Pipeline and Hazardous Materials Safety Administration****Hazardous Materials: Notice of Applications for New Special Permits**

AGENCY: Pipeline and Hazardous Materials Safety Administration (PHMSA), DOT.

ACTION: List of applications for special permits.

SUMMARY: In accordance with the procedures governing the application for, and the processing of, special permits from the Department of Transportation's Hazardous Material regulations, notice is hereby given that the Office of Hazardous Materials Safety has received the application described herein.

DATES: Comments must be received on or before December 22, 2022.

ADDRESSES: Record Center, Pipeline and Hazardous Materials Safety Administration, U.S. Department of Transportation Washington, DC 20590.

Comments should refer to the application number and be submitted in triplicate. If confirmation of receipt of comments is desired, include a self-addressed stamped postcard showing the special permit number.

FOR FURTHER INFORMATION CONTACT:

Donald Burger, Chief, Office of Hazardous Materials Safety General Approvals and Permits Branch, Pipeline and Hazardous Materials Safety Administration, U.S. Department of Transportation, East Building, PHH-13, 1200 New Jersey Avenue Southeast, Washington, DC 20590-0001, (202) 366-4535.

SUPPLEMENTARY INFORMATION: Each mode of transportation for which a particular special permit is requested is indicated by a number in the "Nature of

Application" portion of the table below as follows: 1—Motor vehicle, 2—Rail freight, 3—Cargo vessel, 4—Cargo aircraft only, 5—Passenger-carrying aircraft.

Copies of the applications are available for inspection in the Records Center, East Building, PHH-13, 1200 New Jersey Avenue Southeast, Washington, DC.

This notice of receipt of applications for special permit is published in accordance with part 107 of the Federal hazardous materials transportation law (49 U.S.C. 5117(b); 49 CFR 1.53(b)).

Issued in Washington, DC, on November 10, 2022.

Donald P. Burger,

Chief, General Approvals and Permits Branch.

Application No.	Applicant	Regulation(s) affected	Nature of the special permits thereof
Special Permits Data			
21459-N	Hopkins Holdings LLC	173.306(a)(1)	To authorize the transportation in commerce of 2P receptacles, with capacities exceeding 4 fluid ounces, containing butane as limited quantities. (modes 1, 2)
21461-N	Zhejiang Chumoon Iron-Printing & Tin-Making Co., Ltd.	173.304(d), 173.306(i)(1), 173.167.	To authorize the manufacture, marking, sale and use of a non-refillable, non-DOT specification inside metal container, similar to a DOT 2Q, that contain liquefied and refrigerant gases rather than aerosols. (modes 1, 2, 3, 4)
21463-N	Mission Systems Orchard Park Inc.	173.302a(a)(1)	To authorize the manufacture, mark, sale, and use of non-DOT specification cylinders similar to ISO 11119-2. (modes 1, 2, 3, 4)
21466-N	KMG Electronic Chemicals, Inc.	172.102(c)(4)	To authorize the transportation in commerce of nitric acid in IBCs that are authorized for two years from the date of first fill. (mode 1)
21467-N	General Motors LLC	172.101(j)	To authorize the transportation in commerce of lithium ion batteries exceeding 35 kg net weight aboard cargo-only aircraft. (mode 4)
21469-N	Romeo Systems, Inc	172.101(j)	To authorize the transportation in commerce of lithium batteries exceeding 35 kg by cargo-only aircraft. (mode 4)
21474-N	Yiwu Bluefire Camping Industry Co., Ltd.	173.304a(a)(1), 173.304a(d) ...	To authorize the manufacture, marking, sale and use of a non-DOT specification non-refillable inside container conforming with all regulations applicable to a DOT specification 2P inner non-refillable metal receptacle except for size, testing requirements, and marking. (modes 1, 2, 3)

[FR Doc. 2022-25329 Filed 11-21-22; 8:45 am]

BILLING CODE 4910-60-P

DEPARTMENT OF TRANSPORTATION**Pipeline and Hazardous Materials Safety Administration****Hazardous Materials: Notice of Actions on Special Permits**

AGENCY: Pipeline and Hazardous Materials Safety Administration (PHMSA), DOT.

ACTION: Notice of actions on special permit applications.

SUMMARY: In accordance with the procedures governing the application for, and the processing of, special permits from the Department of Transportation's Hazardous Material regulations, notice is hereby given that the Office of Hazardous Materials Safety has received the application described herein.

DATES: Comments must be received on or before December 22, 2022.

ADDRESSES: Record Center, Pipeline and Hazardous Materials Safety Administration, U.S. Department of Transportation, Washington, DC 20590.

Comments should refer to the application number and be submitted in triplicate. If confirmation of receipt of comments is desired, include a self-addressed stamped postcard showing the special permit number.

FOR FURTHER INFORMATION CONTACT:

Donald Burger, Chief, Office of Hazardous Materials Safety General Approvals and Permits Branch, Pipeline and Hazardous Materials Safety

Administration, U.S. Department of Transportation, East Building, PHH-13, 1200 New Jersey Avenue Southeast, Washington, DC 20590-0001, (202) 366-4535.

SUPPLEMENTARY INFORMATION: Copies of the applications are available for

inspection in the Records Center, East Building, PHH-13, 1200 New Jersey Avenue Southeast, Washington, DC.

This notice of receipt of applications for special permit is published in accordance with part 107 of the Federal

hazardous materials transportation law (49 U.S.C. 5117(b); 49 CFR 1.53(b)).

Issued in Washington, DC, on November 10, 2022.

Donald P. Burger,
Chief, General Approvals and Permits Branch.

Applicatio No.	Applicant	Regulation(s) affected	Nature of the special permits thereof
Special Permits Data—Granted			
20645-M	Walmart Inc	173.159a(c)(2), 173.185(c)(1)(iii), 173.185(c)(1)(iv), 173.185(c)(1)(v), 173.185(c)(3).	To modify the special permit to authorize an additional packaging.
20798-M	Americase, LLC	172.101(j), 173.185(a)(1)(i)	To modify the special permit to authorize an additional packaging system.
21359-N	Thales Alenia Space	172.101(j), 172.300, 172.400, 173.301(f), 173.302a(a)(1), 173.304a(a)(2), 173.56, 173.185(a)(1).	To authorize the transportation in commerce of the satellite transport container (STC) that contains the satellite and certain non-DOT specification containers (satellite assemblies) including low production lithium ion batteries contained in equipment that have not completed all UN tests and exceed 35 kg net weight by cargo-only aircraft, certain Division 2.2 and 2.3 liquefied and compressed gases, unapproved explosives, and other hazardous materials identified in paragraph 6 of this special permit.
21366-N	Our Next Energy Inc	172.101(j), 173.185(a)(1), 173.185(b)(6).	To authorize the transportation in commerce of low production lithium ion battery assemblies exceeding 35 kg net weight aboard cargo-only aircraft.
21377-N	Proterra Inc	172.101(j)	To authorize the transportation in commerce of lithium ion battery assemblies exceeding 35 kg net weight aboard cargo-only aircraft.
21381-N	Jungbunzlauer Inc	173.241	To authorize the transportation in commerce of lactic acid in non-DOT specification intermediate bulk containers.
21393-N	Bollore Logistics Germany GmbH.	173.185(a)(1)	To authorize the transportation in commerce of prototype lithium batteries contained in equipment via cargo-only aircraft.
21394-N	Alucan Entec Sa	173.306(a)(3)(ii), 173.306(a)(3)(iii).	To authorize the manufacture, mark, sale and use of a certain non-DOT specification inside metal containers similar to DOT Specification 2Q inner non-refillable metal receptacle.
21441-N	K&M Transportation Services, LLC.	173.196(b)(2)	To authorize the transportation in commerce of infectious substances in alternative packaging.
21452-N	Toyota Motor Corporation	172.101(j)	To authorize the transportation in commerce of lithium ion battery assemblies exceeding 35 kg net weight aboard cargo-only aircraft.
Special Permits Data—Denied			
20942-M	Better Horse Inc	172.101(i), 172.200(a), 172.320(a), 172.400(a), 172.500(a), 173.60(a), 173.63(b).	To modify the special permit to include IMDG Code regulatory relief in the special permit.
21322-N	Federal Express Corporation ..	175.75(c), 175.75(d)	To authorize the transportation in commerce of certain hazardous materials with relief from the quantity limitations and cargo location requirements under 49 CFR 175.75 (c) and (d).
Special Permits Data—Withdrawn			
21419-M	Space Exploration Technologies Corp.	172.300, 172.400, 173.302a ...	To authorize the transportation in commerce of spacecraft and spacecraft components containing non-DOT specification cylinder which are not marked and labeled in accordance with Part 172.

DEPARTMENT OF TRANSPORTATION**[Docket No. DOT–OST–2022–0120]****Agency Information Collection
Activities: DOT Technical Assistance
PRA****AGENCY:** Office of the Secretary (OST),
Department of Transportation (DOT).**ACTION:** Notice of request for comments.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995, this notice announces the intention of the Office of the Secretary (OST) for a renewal of a currently approved information collection for the DOT Technical Assistance PRA, which is summarized below under Supplementary Information. We are required to publish this notice in the **Federal Register** by the Paperwork Reduction Act of 1995.

DATES: Please submit comments by January 23, 2023.

ADDRESSES: You may send comments within 60 days to the Office of Information and Regulatory Affairs, Office of Management and Budget, 725 17th Street NW, Washington, DC 20503, Attention DOT Desk Officer. All comments received are part of the public record. Comments will generally be posted without change. All comments should include the Docket number DOT–OST–2022–0082.

FOR FURTHER INFORMATION CONTACT: Please email *ThrivingCommunities@dot.gov* or contact Victor Austin at 202–366–2996. Office hours are from 8 a.m. to 5 p.m. EDT, Monday through Friday, except for Federal holidays.

SUPPLEMENTARY INFORMATION:

Title: DOT Technical Assistance PRA.

Background: Bipartisan Infrastructure Law (BIL) enacted as the Infrastructure Investment and Jobs Act (IIJA) (H.R. 3684, Public Law 117–58, also known as the Bipartisan Infrastructure Law or BIL) created several new programs at the US Department of Transportation (DOT) that allow local governments, non-profit organizations, tribal governments, and other political subdivisions of state or local governments to apply directly for DOT discretionary grant funding. In response to President Biden's Executive Order 13985, Advancing Racial Equity and Support for Underserved Communities Through the Federal Government and Executive Order 14008, Tackling the Climate Crisis at Home and Abroad, DOT has included criteria in its notices of funding opportunity to

prioritize the needs of disadvantaged communities for many of these new programs.

The Thriving Communities Initiative will include programs by which DOT will utilize cooperative agreements and procurements with technical assistance and capacity building providers to support communities seeking to advance transformative, equitable, and climate-friendly infrastructure projects that benefit disadvantaged communities. Specifically, these include the Thriving Communities program, the Rural and Tribal Infrastructure Assistance Pilot Program (see § 21205 of Pub. L. 117–58), and Asset Concession and Innovative Finance Assistance Program (see 23 U.S.C. 611 as amended by § 71001 of Pub. L. 117–58).

DOT will utilize a Letter of Interest (LOI) or use a simplified in-take form from communities interested in receiving technical assistance and capacity building through these programs. Technical assistance and capacity building is offered by the Government at no charge and with no required non-federal share.

Establishment of the program has two distinct tasks: (a) contracting of technical assistance advisors through a Notice of Funding Opportunity (NOFO) or existing procurement vehicles; and (b) recruitment of project sponsors who will receive technical assistance services. Responding to both will occur on a voluntary basis, utilizing an electronic platform.

For item A, eligible applicants to provide technical assistance through the Thriving Communities program will request cooperative agreement funding through an application process in response to a published NOFO. The application is planned as a one-time information collection. DOT estimates that it will take approximately 20 hours to complete the NOFO application process used to select capacity builders under the Thriving Communities program. DOT estimates the recipients of Thriving Communities program funding will spend another 4 hours, annually, submitting post-award reports. In addition, reporting requirements will be submitted by the select capacity building providers and technical assistance recipients during the implementation, and evaluation phases.

For the Rural and Tribal Infrastructure Assistance Pilot Program and Asset Concession and Innovative Finance Assistance Program, advisors and

technical assistance providers will be contracted using existing procurement vehicles. Estimated time required for these programs will be 4 hours annually.

For item B, the intake form to be used by communities seeking technical assistance is estimated to take no more than 1 hour to complete. Recipients of technical assistance support are estimated to spend no more than 2 hours annually providing evaluation metrics.

Respondents to Item A (technical assistance providers): for-profit companies, non-profit organizations, or other technical assistance providers.

Respondents to Item B (requestors of technical assistance): philanthropic entities, non-profit organizations, other Federal agencies, state or local governments and their agencies, and Indian Tribes.

Frequency: Once a year.

Estimated Average Burden per Response: Approximately 24 hours for applicants to complete the application process and reporting requirements and an estimated 30 applicants. Approximately seven hours to complete the in-take form and evaluation metrics and an estimated 20 project sponsors.

Estimated Total Annual Burden Hours: Approximately 860 hours.

Public Comments Invited: You are asked to comment on any aspect of this information collection, including: (1) Whether the proposed collection is necessary for the DOT's performance; (2) the accuracy of the estimated burdens; (3) ways for the DOT to enhance the quality, usefulness, and clarity of the collected information; and (4) ways that the burden could be minimized, including the use of electronic technology, without reducing the quality of the collected information. The agency will summarize and/or include your comments in the request for OMB's clearance of this information collection.

Authority: The Paperwork Reduction Act of 1995; 44 U.S.C. chapter 35, as amended; 23 U.S.C. 134 and 135; and 23 CFR chapter 1, subchapter E, part 450.

Dated: November 17, 2022.

Mariia Zimmerman,
Strategic Advisor for Technical Assistance and Community Solutions, Office of the Secretary, US Department of Transportation.
[FR Doc. 2022–25380 Filed 11–21–22; 8:45 am]

BILLING CODE 4910–9P–P

DEPARTMENT OF THE TREASURY

Dates:

Community Development Financial
Institutions Fund**Funding Opportunity Title: Notice of
Allocation Availability (NOAA) Inviting
Applications for the Calendar Year
(CY) 2022 Allocation Round of the New
Markets Tax Credit (NMTC) Program***Announcement type:* Announcement
of NMTC Allocation availability.

TABLE 1—CY 2022 ALLOCATION ROUND NMTC PROGRAM CRITICAL DEADLINES FOR APPLICANTS

Description	Deadline/date	Time (eastern time—ET)	Submission method
Community Development Entity (CDE) Certification Application	December 2, 2022.	11:59 p.m. ET ...	Electronically via the Awards Management Information Sys- tem (AMIS).
Request to modify CDE certification service area	December 2, 2022.	11:59 p.m. ET ...	Electronically via AMIS.
Subsidiary CDE Certification Application for meeting Qualified Equity Investment (QEI) issuance thresholds.	December 2, 2022.	11:59 p.m. ET ...	Electronically via AMIS.
CY 2022 Application Registration	December 15, 2022.	5:00 p.m. ET	Electronically via AMIS.
Last date to contact CDFI Fund staff	January 24, 2023.	5:00 p.m. ET	Electronically via AMIS.
CY 2022 Allocation Application (including required Attachments)	January 26, 2023.	5:00 p.m. ET	Electronically via AMIS.
Amendment request to add Subsidiary CDEs to Allocation Agree- ments for meeting QEI issuance thresholds.	March 6, 2023 ...	11:59 p.m. ET ...	Electronically via AMIS.
Amendment request to remove a Controlling Entity from Allocation Agreement(s).	March 6, 2023 ...	11:59 p.m. ET ...	Electronically via AMIS.
QEI Issuance and making Qualified Low Income Community Invest- ments (QLICs) by.	May 4, 2023	11:59 p.m. ET ...	Not Applicable.
Report QEIs and certify QLICs by	May 11, 2023	11:59 p.m. ET ...	Electronically via AMIS.

Executive Summary: This NOAA is issued in connection with the CY 2022 allocation round (Allocation Round) of the New Markets Tax Credit Program (NMTC Program), as authorized by Title I, subtitle C, section 121 of the Community Renewal Tax Relief Act of 2000 (Pub. L. 106–554) as amended. Through the NMTC Program, the Community Development Financial Institutions Fund (CDFI Fund) provides authority to certified CDEs to offer an incentive to investors in the form of tax credits over seven years, which is expected to stimulate the provision of private investment capital that, in turn, will facilitate economic and community development in Low-Income Communities. Through this NOAA, the CDFI Fund announces the availability of \$5 billion of NMTC Allocation authority in this Allocation Round. In this NOAA, the CDFI Fund specifically addresses how a CDE may apply to receive an

allocation of NMTCs, the competitive procedure through which NMTC Allocations will be made, and the actions that will be taken to ensure that proper allocations are made to appropriate entities.

I. Allocation Availability Description*A. Programmatic changes from the CY 2021 allocation round:*

1. Prior QEI Issuance Requirements: Prior-year NMTC Allocatees will be subject to minimum thresholds for QEI issuance and closing of QLICs with respect to their prior-year NMTC Allocations. These thresholds and deadlines have been revised in comparison to the CY 2021 NOAA. See Section III. A.5(a) of this NOAA for additional details.

II. Allocation Information

A. Allocation amounts: Pursuant to the Taxpayer Certainty and Disaster Tax Relief Act of 2020, the CDFI Fund

expects that it may allocate to CDEs the authority to issue to their investors the aggregate amount of \$5 billion in equity as to which NMTCs may be claimed, as permitted under IRC § 45D(f)(1)(D). Pursuant to this NOAA, the CDFI Fund anticipates that it may issue up to \$100 million in tax credit investment authority per Allocatee. The CDFI Fund, in its sole discretion, reserves the right to allocate amounts in excess of or less than the anticipated maximum allocation amount should the CDFI Fund deem it appropriate. The CDFI Fund reserves the right to allocate NMTC authority to any, all, or none of the entities that submit applications in response to this NOAA, and in any amounts it deems appropriate.

B. Type of award: NMTC Program awards are made in the form of allocations of tax credit investment authority.

C. Program guidance and regulations: This NOAA describes application and NMTC Allocation requirements for this Allocation Round of the NMTC Program and should be read in conjunction with: (i) the final NMTC Program Income Tax Regulations issued by the Internal Revenue Service (IRS) (26 CFR 1.45D–1, published on December 28, 2004), as amended and related guidance, notices and other publications; and (ii) the application and related materials for this Allocation Round. All such materials may be found on the CDFI Fund's website at <https://www.cdfifund.gov>. The CDFI Fund requires Applicants to review these documents. Capitalized terms used, but not defined, in this NOAA have the respective meanings assigned to them in the NMTC Program Allocation Application, Internal Revenue Code (IRC) § 45D or the IRS NMTC regulations. In the event of any inconsistency between this NOAA, the Allocation Application, and guidance issued by the CDFI Fund thereto, IRC § 45D or the IRS NMTC Regulations, the provisions of IRC § 45D and the IRS NMTC Regulations shall govern.

D. Allocation Agreement: Each Allocatee must sign an Allocation Agreement, which must be countersigned by the CDFI Fund, before the NMTC Allocation is effective. The Allocation Agreement contains the terms and conditions of the NMTC Allocation. For further information, see Section VI.B of this NOAA.

E. Statutory and national policy requirements: The CDFI Fund will manage and administer the NMTC Program in a manner so as to ensure that NMTC Allocations associated programs are implemented in full accordance with the U.S. Constitution, Federal Law, statutory, and public policy requirements: including, but not limited to, those protecting free speech; religious liberty; public welfare; the environment; and prohibiting discrimination.

III. Eligibility

A. Eligible Applicants: IRC § 45D specifies certain eligibility requirements that each Applicant must meet to be eligible to apply for an allocation of NMTCs. The following sets forth additional detail and certain additional dates that relate to the submission of applications under this NOAA for the available NMTC Allocation authority.

1. *CDE certification:* For purposes of this NOAA, the CDFI Fund will not

consider an application for an allocation of NMTCs unless: (a) the Applicant is certified as a CDE at the time the CDFI Fund receives its NMTC Program Allocation Application; or (b) the Applicant submits an application for certification as a CDE through AMIS by the deadline in Table 1. Applicants for CDE certification may obtain information regarding CDE certification and the CDE Certification Application process in AMIS on the CDFI Fund's website at <https://www.cdfifund.gov/programs-training/certification/cde/Pages/default.aspx>.

The CDFI Fund will not provide NMTC Allocation authority to Applicants that are not certified as CDEs or to entities that are certified as Subsidiary CDEs.

If an Applicant that has already been certified as a CDE wishes to change its designated CDE Service Area for this Allocation Round, then it must submit a CDE Service Area Amendment Application to request such a change from the CDFI Fund, and the application must be received by the CDFI Fund by the deadline listed in Table 1. A request to change a CDE's Service Area will need to include the revised service area designation and updated accountability information that demonstrates that the CDE has the required representation from Low-Income Communities in the revised CDE Service Area.

2. *Repayment or Refinancing of QEI with QLICI Proceeds:* An applicant must commit that it will not permit the use of the proceeds of QEIs to make QLICIs in Qualified Active Low-Income Community Businesses (QALICBs) where QLICI proceeds are used, in whole or in part, to repay or refinance a debt or equity provider whose capital was used to fund the QEI, or are used to repay or refinance any Affiliate of such a debt or equity provider, except where: (i) the QLICI proceeds are used to repay or refinance documented reasonable expenditures that are directly attributable to the qualified business of the QALICB, and such reasonable expenditures were incurred no more than 24 months prior to the QLICI closing date; or (ii) no more than five percent of the total QLICI proceeds from the QEI are used to repay or refinance documented reasonable expenditures that are directly attributable to the qualified business of the QALICB. Refinance includes transferring cash or property, directly or

indirectly, to the debt or equity provider or an Affiliate of the debt or equity provider.

3. *Do Not Pay:* The CDFI Fund will contact the Do Not Pay Business Center to ensure that an Applicant, its Controlling Entity, and any Affiliate(s) are not prohibited from receiving federal funds. An Applicant, its Controlling Entity, and any Affiliate(s) reported by the Do Not Pay Business Center as having a pending or delinquent debt to the Federal government will be required to demonstrate that it has resolved such pending or delinquent debt. Applicants that fail to demonstrate resolution of such pending or delinquent debt to the Federal government will be found ineligible to receive an allocation.

4. *Controlling Entities:* An organization that was a Controlling Entity to an Allocatee in a prior round(s) and subsequently separated from that Allocatee, as a result of an amendment to the Allocation Agreement(s), may not claim the NMTC-related track record of such Allocatee.

5. *Prior award recipients or Allocatees:* Applicants must be aware that success in a prior application or allocation round of any of the CDFI Fund's programs is not indicative of success under this NOAA. For purposes of this NOAA, and eligibility determinations, the CDFI Fund will consider an Affiliate to be any entity that meets the definition of Affiliate as defined in the NMTC Allocation Application materials, or any entity otherwise identified as an Affiliate by the Applicant in its NMTC Allocation Application materials.

Prior award recipients of any CDFI Fund program are eligible to apply under this NOAA, except as follows:

(a) *Prior Allocatees and Qualified Equity Investment (QEI) issuance and Qualified Low Income Community Investment (QLICI) requirements:* CDEs that are Allocatees under the CY 2017 to the CY 2021 rounds must finalize at least the percentage of QEIs noted in Table 2 for each NMTC Allocation round and use at least the percentage of those QEIs designated in Schedule 1, section 3.2(j) of their Allocation Agreements to make QLICIs by the deadline in Table 1. CDEs that are Allocatees under the CY 2017 to the CY 2021 allocation rounds and CDEs that are Allocatees designated as Rural CDEs in their CY 2021 Allocation Agreement must meet the following thresholds.

TABLE 2—QEI ISSUANCE AND QLICI REQUIREMENTS

Prior round allocation	Finalized QEI requirement (percent)	Rural CDE finalized QEI requirement (percent)	QLICIs
CY 2017	100	100	As stated in Schedule 1, Section 3.2(j) of the applicable Allocation Agreement.
CY 2018	90	90	
CY 2019	70	70	
CY 2020	40	40	
CY 2021	20	0	

In addition to the requirements noted above, a CDE is not eligible to receive an NMTC Allocation pursuant to this NOAA if an Affiliate of the Applicant is a prior Allocatee and has not met the minimum QEI issuance and QLICI thresholds as set forth in Table 2 for Allocatees in the prior allocation rounds of the NMTC Program.

For purposes of this section of the NOAA, the CDFI Fund will only recognize as “finalized” those QEIs that have been properly reported in AMIS Allocation and QEI Tracking System for Qualified Equity Investments (AQEIs) by the deadline in Table 1. Allocatees and their Subsidiary Allocatees, if any, are advised to access AMIS to record each QEI that they issue to an investor in exchange for cash. Furthermore, the CDFI Fund will only recognize QLICIs that have been certified in AMIS by the deadline in Table 1. Instructions on recording a QEI and QLICIs in AMIS are available at <https://www.cdfifund.gov/amisreporting>. Applicants may be required, upon notification from the CDFI Fund, to submit documentation to substantiate the required QEI issuance and QLICI thresholds.

Any prior Allocatee that requires action by the CDFI Fund (*i.e.*, certifying a subsidiary entity as a CDE; adding a subsidiary CDE to an Allocation Agreement; etc.) in order to meet the QEI issuance requirements above must submit a CDE Certification Application for Subsidiary CDEs and/or Allocation Agreement amendment requests by the respective deadlines in Table 1, in order to guarantee that the CDFI Fund completes all necessary approvals prior to the QEI issuance deadline in Table 1. Applicants for Subsidiary CDE certification may obtain information regarding CDE certification and the CDE Certification Application process in AMIS on the CDFI Fund’s website at <https://www.cdfifund.gov/programs-training/certification/cde/Pages/default.aspx>.

(b) *Pending determination of noncompliance or default:* If an Applicant is a prior award recipient or Allocatee under any CDFI Fund

program and if: (i) it has demonstrated noncompliance with a previous assistance or award agreement or default under a previous Allocation Agreement or pursuant to any other agreement under any CDFI Fund program; and (ii) the entity has been given a timeframe to cure the noncompliance or default, the CDFI Fund will consider the Applicant’s application under this NOAA during the time period given for the entity to cure the noncompliance or default, and until such time as the CDFI Fund makes a final determination that the entity is in noncompliance or default. Further, if an Affiliate of the Applicant is a prior CDFI Fund award recipient or Allocatee and if such entity: (i) has demonstrated noncompliance with a previous assistance or award agreement or default under a previous Allocation Agreement or pursuant to any other agreement under any CDFI Fund program; and (ii) the entity has been given a timeframe to cure the noncompliance or default, then the CDFI Fund will consider the Applicant’s application under this NOAA during the time period given for the entity to cure the noncompliance or default, and until such time as the CDFI Fund makes a final determination that the entity is in noncompliance or default.

(c) *Noncompliance or default status:* The CDFI Fund will not consider an application submitted by an Applicant that is a prior CDFI Fund award recipient or Allocatee under any CDFI Fund program if, as of the application deadline of this NOAA: (i) the CDFI Fund has made a final determination that such Applicant is noncompliant with a previously executed assistance or award agreement, or in default of a previously executed Allocation Agreement or any other agreement under any CDFI Fund program; and (ii) the CDFI Fund has provided written notification of such final determination to the Applicant; and (iii) the default occurs during the time period beginning 12 months prior to the application deadline and ending with the CY 2022 allocation award announcement.

Further, the CDFI Fund will not consider an application submitted by an Applicant with an Affiliate that is a prior award recipient or Allocatee under any CDFI Fund Program if, as of the application deadline of this NOAA: (i) the CDFI Fund has made a final determination that such Affiliate is noncompliant with a previously executed assistance or award agreement, or in default of a previously executed Allocation Agreement or any other agreement under any CDFI Fund program; (ii) the CDFI Fund has provided written notification of such final determination to the Affiliate; and (iii) the noncompliance or default occurs during the time period beginning 12 months prior to the application deadline and ending with the CY 2022 allocation award announcement.

(d) *Contacting the CDFI Fund:* Accordingly, Applicants that are prior award recipients and/or Allocatees under any CDFI Fund program are advised to comply with the requirements specified in assistance, allocation and/or award agreement(s). All outstanding reports and compliance questions should be directed to the Office of Compliance Monitoring and Evaluation (OCME) through a Service Request initiated in AMIS. Requests submitted less than 30 calendar days prior to the application deadline may not receive a response before the application deadline.

The CDFI Fund will respond to Applicants’ reporting, compliance and CDE certification inquiries Monday through Friday, between the hours of 9:00 a.m. and 5:00 p.m. ET, starting the date of publication of this NOAA through the “Last date to contact CDFI Fund staff” specified in Table 1. Inquiries received after the “Last date to contact the CDFI Fund staff” will be responded to after the Allocation Application deadline.

6. *Failure to accurately respond to a question in the Assurances and Certifications section of the application, submit the required written explanation, or provide any updates:* In its sole discretion, the CDFI Fund may deem the

Applicant's application ineligible, if the CDFI Fund determines that the Applicant inaccurately responded to a question, accurately responded to a question, but failed to submit a required written explanation, or failed to notify the CDFI Fund of any changes to the information submitted between the date of application and the date the Allocatee executes the Allocation Agreement, with respect to the Assurances and Certifications. In making this determination, the CDFI Fund will take into consideration, among other factors, the materiality of the question, the substance of any supplemental responses provided, and whether the information in the Applicant's supplemental responses would have a material adverse effect on the Applicant, its financial condition or its ability to perform under an Allocation Agreement, should the Applicant receive an allocation.

7. Entities that propose to transfer NMTCs to Subsidiary CDEs: Both for-profit and non-profit CDEs may apply for NMTC Allocation authority, but only a for-profit CDE is permitted to provide NMTCs to its investors. A non-profit Applicant wishing to apply for an NMTC Allocation must demonstrate, prior to entering into an Allocation Agreement with the CDFI Fund, that: (i) it controls one or more Subsidiary CDEs that are for-profit entities; and (ii) it intends to transfer the full amount of any NMTC Allocation it receives to said Subsidiary CDEs.

An Applicant wishing to transfer all or a portion of its NMTC Allocation to a Subsidiary CDE is not required to create the Subsidiary prior to submitting an NMTC Allocation Application to the CDFI Fund. However, the Subsidiary entities must be certified as CDEs by the CDFI Fund, and enjoined as parties to the Allocation Agreement at closing or by amendment to the Allocation Agreement after closing.

The CDFI Fund requires a non-profit Applicant to submit a CDE Certification Application to the CDFI Fund on behalf of at least one for-profit Subsidiary within 45 days after the non-profit Applicant receives notification from the CDFI Fund of its allocation award, as such Subsidiary must be certified as a CDE prior to entering into an Allocation Agreement with the CDFI Fund. The CDFI Fund reserves the right to rescind the award if a non-profit Applicant that does not already have a certified for-profit Subsidiary CDE fails to submit a CDE Certification Application for one or more for-profit Subsidiaries within 45 days of the date it receives notification from the CDFI Fund of its allocation award.

8. Entities that submit applications together with Affiliates; applications from common enterprises:

(a) As part of the Allocation Application review process, the CDFI Fund will evaluate whether Applicants are Affiliates, as such term is defined in the Allocation Application. If an Applicant and its Affiliate(s) wish to submit Allocation Applications, they must do so collectively, in one application; an Applicant and its Affiliate(s) may not submit separate Allocation Applications. If Affiliated entities submit multiple applications, the CDFI Fund will reject all such applications received, except for those state-owned or state-controlled governmental Affiliated entities. In the case of state-owned or state-controlled governmental entities, the CDFI Fund may accept applications submitted by different government bodies within the same state, but only to the extent the CDFI Fund determines that the business strategies and/or activities described in such applications, submitted by separate entities, are distinctly dissimilar and/or are operated and/or managed by distinctly dissimilar personnel, including staff, board members and identified consultants. In such cases, the CDFI Fund reserves the right to limit award amounts to such entities to ensure that the entities do not collectively receive more than the \$100 million cap.

If the CDFI Fund determines that the applications submitted by different government bodies in the same state are not distinctly dissimilar and/or operated and/or managed by distinctly dissimilar personnel, it will reject all such applications.

(b) For purposes of this NOAA, the CDFI Fund will also evaluate whether each Applicant is operated or managed as a "common enterprise" with another Applicant in this Allocation Round using the following indicia, among others: (i) whether different Applicants have the same individual(s), including the Authorized Representative, staff, board members and/or consultants, involved in day-to-day management, operations and/or investment responsibilities; (ii) whether the Applicants have business strategies and/or proposed activities that are so similar or so closely related that, in fact or effect, they may be viewed as a single entity; and/or (iii) whether the applications submitted by separate Applicants contain significant narrative, textual or other similarities such that they may, in fact or effect, be viewed as substantially identical applications. In such cases, the CDFI Fund will reject all applications received from such entities.

(c) Furthermore, an Applicant that receives an NMTC Allocation in this Allocation Round (or its Subsidiary Allocatee) may not become an Affiliate of or member of a common enterprise (as defined above) with another Applicant that receives an NMTC Allocation in this Allocation Round (or its Subsidiary Allocatee) at any time after the submission of an Allocation Application under this NOAA. This prohibition, however, generally does not apply to entities that are commonly controlled solely because of common ownership by QEI investors. This requirement will also be a term and condition of the Allocation Agreement (see Section VI.B of this NOAA and additional application guidance materials on the CDFI Fund's website at <https://www.cdfifund.gov> for more details).

9. Entities created as a series of funds:

An Applicant whose business structure consists of an entity with a series of funds must apply for CDE certification for each fund. If such an Applicant represents that it is properly classified for Federal tax purposes as a single partnership or corporation, it may apply for CDE certification as a single entity. If an Applicant represents that it is properly classified for Federal tax purposes as multiple partnerships or corporations, then it must submit a CDE Certification Application for the Applicant and each fund it would like to participate in the NMTC Program, and each fund must be separately certified as a CDE. Applicants should note, however, that receipt of CDE certification as a single entity or as multiple entities is not a determination that an Applicant and its related funds are properly classified as a single entity or as multiple entities for Federal tax purposes. Regardless of whether the series of funds is classified as a single partnership or corporation or as multiple partnerships or corporations, an Applicant may not transfer any NMTC Allocations it receives to one or more of its funds unless the fund is a certified CDE that is a Subsidiary of the Applicant, enjoined to the Allocation Agreement as a Subsidiary Allocatee.

10. Entities that are Bank Enterprise Award Program (BEA Program) award recipients: An insured depository institution investor (and its Affiliates and Subsidiaries) may not receive an NMTC Allocation in addition to a BEA Program award for the same investment in a CDE. Likewise, an insured depository institution investor (and its Affiliates and Subsidiaries) may not receive a BEA Program award in addition to an NMTC Allocation for the same investment in a CDE.

IV. Application and Submission Information

A. Address to request application package: Applicants must submit applications electronically under this NOAA, through the CDFI Fund's AMIS. Following the publication of this NOAA, the CDFI Fund will make the electronic Allocation Application available on its website at <https://www.cdfifund.gov>.

B. Application content requirements: Detailed application content requirements are found in the application related to this NOAA. Applicants must submit all materials described in and required by the application by the applicable deadlines. Applicants will not be afforded an opportunity to provide any missing materials or documentation, except, if necessary and at the request of the CDFI Fund. Electronic applications must be submitted solely by using the format made available via AMIS. Additional information, including instructions relating to the submission of supporting information (e.g., the Controlling Entity's representative signature page, Assurances and Certifications supporting documents, investor letters, organizational charts), is set forth in further detail in the CY 2022 NMTC Application—AMIS Navigation Guide for this Allocation Round. An application must include a valid and current Employer Identification Number (EIN) issued by the Internal Revenue Service (IRS) and assigned to the Applicant and, if applicable, its Controlling Entity. Electronic applications without a valid EIN are incomplete and cannot be transmitted to the CDFI Fund. For more information on obtaining an EIN, please contact the IRS at (800) 829-4933 or www.irs.gov. Do not include any personal Social Security Numbers as part of the application.

C. NMTC Application Registration (Application Registration): CY 2022 Allocation Round Applicants are first required to complete and save the Application Registration section of the NMTC Allocation Application in AMIS by the Application Registration deadline in order to be able to submit the remaining sections of the CY 2022 Allocation Application by the Application deadline. Applicants that do not complete and save the Application Registration by the Application Registration deadline, will not be able to subsequently submit a CY 2022 Allocation Application in AMIS.

An Applicant may not submit more than one application in response to this NOAA. In addition, as stated in Section III.A.8 of this NOAA, an Applicant and

its Affiliates must collectively submit only one Allocation Application; an Applicant and its Affiliates may not submit separate Allocation Applications except as outlined in Section III.A.8 above. Once an application is submitted, an Applicant will not be allowed to change any element of its application.

D. Form of application submission: Applicants may only submit applications under this NOAA electronically via AMIS. Applications and required attachments sent by mail, facsimile, or email will not be accepted. Submission of an electronic application will facilitate the processing and review of applications and the selection of Allocatees; further, it will assist the CDFI Fund in the implementation of electronic reporting requirements.

Electronic applications must be submitted solely by using the CDFI Fund's website and must be sent in accordance with the submission instructions provided in the CY 2022 NMTC Application—AMIS Navigation Guide for this Allocation Round. AMIS will only permit the submission of applications in which all required questions and tables are fully completed. Additional information, including instructions relating to the submission of supporting information (e.g., the Controlling Entity's representative signature page, Assurances and Certifications supporting documents, investor letters, and organizational charts) is set forth in further detail in the CY 2022 NMTC Application—AMIS Navigation Guide for this Allocation Round.

E. Application submission dates and times: Electronic applications must be received by the Allocation Application deadline in Table 1. Electronic applications cannot be transmitted or received after Allocation Application deadline in Table 1. In addition, Applicants must electronically submit supporting information (e.g., the Controlling Entity's representative signature page, investor letters, and organizational charts). The Controlling Entity's representative signature page, investor letters, and organizational charts must be submitted on or before the Application deadline in Table 1. For details, see the instructions provided in the CY 2022 NMTC Application—AMIS Navigation Guide for this Allocation Round on the CDFI Fund's website.

Applications and other required documents received after this date and time will be rejected. Please note that the document submission deadlines in this NOAA and/or the Allocation Application are strictly enforced.

F. Intergovernmental Review: Not applicable.

G. Funding Restrictions: For allowable uses of investment proceeds related to an NMTC Allocation, please see 26 U.S.C. 45D and the final regulations issued by the Internal Revenue Service (26 CFR 1.45D-1, published December 28, 2004 and as amended) and related guidance. Please see Section I, above, for the Programmatic Changes of this NOAA.

H. Paperwork Reduction: Under the Paperwork Reduction Act (44 U.S.C. chapter 35), an agency may not conduct or sponsor a collection of information, and an individual is not required to respond to a collection of information, unless it displays a valid OMB control number. Pursuant to the Paperwork Reduction Act, the application has been assigned the following control number: 1559-0016.

V. Application Review Information

A. Review and selection process: All Allocation Applications will be reviewed for eligibility and completeness. To be complete, the application must contain, at a minimum, all information described as required in the application form. An incomplete application will be rejected. Once the application has been determined to be eligible and complete, the CDFI Fund will conduct the substantive review of each application in two parts (Phase 1 and Phase 2) in accordance with the criteria and procedures generally described in this NOAA and the Allocation Application.

In Phase 1, two reviewers will evaluate and score the Business Strategy and Community Outcomes sections of each application. An Applicant must exceed a minimum overall aggregate base score threshold and exceed a minimum aggregate section score threshold in each scored section in order to advance from the Phase 1 to the Phase 2 part of the substantive review process. In Phase 2, the CDFI Fund will rank Applicants and determine the dollar amount of allocation authority awarded in accordance with the procedures set forth below.

B. Criteria:

1. Business Strategy (25-point maximum):

(a) When assessing an Applicant's business strategy, reviewers will consider, among other things: the Applicant's products, services and investment criteria; a pipeline of potential business loans or investments consistent with an Applicant's request for an NMTC Allocation; the prior performance of the Applicant or its Controlling Entity, particularly as it

relates to making similar kinds of investments as those it proposes to make with the proceeds of QEIs; the Applicant's prior performance in providing capital or technical assistance to disadvantaged businesses or communities; and the extent to which the Applicant intends to make QLICs in one or more businesses in which persons unrelated to the entity hold a majority equity interest.

Under the Business Strategy criterion, an Applicant will generally score well to the extent that it will deploy debt or investment capital in products or services which are flexible or non-traditional in form and on better terms than available in the marketplace. An Applicant will also score well to the extent that, among other things: (i) it has identified a set of clearly-defined potential borrowers or investees; (ii) it describes the due diligence it will conduct prior to making QLICs to determine whether a QALICB will remain financially viable and operational; (iii) it has a track record of successfully deploying loans or equity investments and providing services similar to those it intends to provide with the proceeds of QEIs; (iv) its projected dollar volume of NMTC Allocation deployment is supported by its track record of deployment; and (v) in the case of an Applicant proposing to purchase loans from CDEs, the Applicant will require the CDE selling such loans to re-invest the proceeds of the loan sale to provide additional products and services to Low-Income Communities.

(b) *Priority Points*: In addition, as provided by IRC § 45D(f)(2), the CDFI Fund will ascribe additional points to entities that meet one or both of the statutory priorities. First, the CDFI Fund will give up to five additional points to any Applicant that has a record of having successfully provided capital or technical assistance to disadvantaged businesses or communities. Second, the CDFI Fund will give five additional points to any Applicant that intends to satisfy the requirement of IRC § 45D(b)(1)(B) by making QLICs in one or more businesses in which persons unrelated (within the meaning of IRC § 267(b) or IRC § 707(b)(1)) to an Applicant (and the Applicant's Subsidiary CDEs, if the Subsidiary Allocatee makes the QLIC) hold the majority equity interest. Applicants may earn points for one or both statutory priorities. Thus, Applicants that meet the requirements of both priority categories can receive up to a total of ten additional points. A record of having successfully provided capital or technical assistance to disadvantaged

businesses or communities may be demonstrated either by the past actions of an Applicant itself or by its Controlling Entity (e.g., where a new CDE is established by a nonprofit corporation with a history of providing assistance to disadvantaged communities). An Applicant that receives additional points for intending to make investments in unrelated businesses and is awarded an NMTC Allocation must meet the requirements of IRC § 45D(b)(1)(B) by investing substantially all of the proceeds from its QEIs in unrelated businesses. The CDFI Fund will include an Applicant's priority points when ranking Applicants during Phase 2 of the review process, as described below.

2. *Community Outcomes (25-point maximum)*: In assessing the potential benefits to Low-Income Communities that may result from the Applicant's proposed investments, reviewers will consider, among other things, the degree to which the Applicant is likely to: (i) achieve significant and measurable community development outcomes in its Low-Income Communities; (ii) invest in particularly economically distressed markets including areas identified in the Allocation Application; (iii) engage with local communities regarding investments; and (iv) involve community representatives in the governing board and/or advisory board in approving investment criteria or decisions.

An Applicant will generally score well under this section to the extent that, among other things: (a) it will generate clear and well supported community development outcomes; (b) it has a track record of producing quantitative and qualitative community outcomes that are similar to those projected to be achieved with an NMTC Allocation; (c) it is working in particularly economically distressed or otherwise underserved communities; (d) its activities are part of a broader community or economic development strategy; (e) it demonstrates a track record of community engagement around past investment decisions; and (f) it ensures that an NMTC investment into a project or business is supported by and will be beneficial to Low-Income Persons and residents of Low-Income Communities.

C. Phase 2 Evaluation:

1. *Application Ranking and Anomaly Reviews*: Using the numeric scores from Phase 1, Applicants are ranked on the basis of each Applicant's combined scores in the Business Strategy and Community Outcomes sections of the application plus one half of the priority points. If, in the case of a particular

application, a reviewer's total base score or section score(s) (in one or more of the two application scored sections) varies significantly from the other reviewer's total base scores or section scores for such application, the CDFI Fund may, in its sole discretion, obtain the evaluation and numeric scoring of an additional third reviewer to determine whether the anomalous score should be replaced with the score of the additional third reviewer.

2. *Late Reports*: In the case of an Applicant or any Affiliates that have previously received an award or NMTC Allocation from the CDFI Fund through any CDFI Fund program, the CDFI Fund will deduct up to five points from the Applicant's rank score for the Applicant's (or its Affiliate's) failure to meet any of the reporting deadlines set forth in any assistance, award or Allocation Agreement(s), if the reporting deadlines occurred during the period from January 14, 2022 to the application deadline in this NOAA.

3. *Prior Year Allocatees*: In the case of Applicants (or their Affiliates) that are prior year Allocatees, the CDFI Fund will review the activities of the prior year Allocatee to determine whether the entity has: (a) effectively utilized its prior-year NMTC Allocations in a manner generally consistent with the representations made in the relevant Allocation Application (including, but not limited to, the proposed product offerings, business type, fees and markets served (i.e. service area) and notable relationships); (b) issued QEIs and closed QLICs in a timely manner; and (c) substantiated a need for additional NMTC Allocation authority. The CDFI Fund will use this information in determining whether to reject or reduce the allocation award amount of its NMTC Allocation Application.

An Applicant will be evaluated more favorably under Part V. of the Application to the extent that it clearly explains: (i) how it ensures that the NMTCs allocated to QALICBs did not exceed the amount necessary to assure QALICB feasibility; (ii) the community outcomes or benefits that were generated as a result of the transaction; (iii) source(s) and amount(s) of leveraged debt from all sources; (iv) the NMTC-related fees and third-party expenses paid by the QALICB or the QALICB's Affiliates, including actions taken to control expenses paid by QALICBs and investors; and (v) quantifies the value of the investment acquired by the QALICBs at the end of the seven-year credit period, to the extent the Applicant's past transactions have been structured to allow QALICBs

to acquire a portion of *QLICs* at the end of the seven-year credit period. An Applicant will also be evaluated favorably to the extent the activities undertaken with the NMTC dollars are consistent with the business strategy presented in the relevant Allocation Application (e.g. product offerings; business type; fees and markets served; notable relationships, etc.).

4. Management Capacity: In assessing an Applicant's management capacity, the CDFI Fund will consider, among other things, the current and planned roles, as well as qualifications of the Applicant's (and Controlling Entity's, if applicable): principals; board members; management team; and other essential staff or contractors, with specific focus on: experience in providing loans; equity investments or financial counseling and other services, including activities similar to those described in the Applicant's business strategy; asset management and risk management experience; experience with fulfilling compliance requirements of other governmental programs, including other tax credit programs; and the Applicant's (or its Controlling Entity's) financial health. CDFI Fund evaluators will also consider the extent to which an Applicant has protocols in place to ensure ongoing compliance with NMTC Program requirements and the Applicant's projected income and expenses related to managing an NMTC Allocation.

An Applicant will be generally evaluated more favorably under this section to the extent that its management team or other essential personnel have experience in: (a) identifying and underwriting loans and/or equity investments or providing financial counseling and other services in Low-Income Communities, if applicable, particularly those likely to be served with *QLICs* from the Applicant; (b) asset and risk management; and (c) fulfilling government compliance requirements, particularly tax credit program compliance. An Applicant will also be evaluated favorably to the extent it clearly explains its due diligence when providing businesses with financing or investment; demonstrates strong financial health and a high likelihood of remaining a going-concern, including support from the Controlling Entity, if applicable; it clearly explains its NMTC fees as well as levels of income and expenses; has policies and systems in place to ensure portfolio quality, ongoing compliance with NMTC Program requirements; and, if it is a Federally-insured financial institution, has its most recent Community

Reinvestment Act (CRA) rating as "outstanding."

5. Capitalization Strategy: When assessing an Applicant's capitalization strategy, the CDFI Fund will consider, among other things: the key personnel of the Applicant (or Controlling Entity) and their track record of raising capital, particularly from for-profit investors; the extent to which the Applicant has secured investments or commitments to invest in NMTC (if applicable), or indications of investor interest commensurate with its requested amount of NMTC Allocations, or, if a prior Allocatee, the track record of the Applicant or its Affiliates in raising Qualified Equity Investments in the past five years; the Applicant's strategy for identifying additional investors, if necessary, including the Applicant's (or its Controlling Entity's) prior performance with raising equity from investors, particularly for-profit investors; the distribution of the economic benefits of the tax credit; and the extent to which the Applicant intends to invest the proceeds from the aggregate amount of its QEIs at a level that exceeds the requirements of IRC § 45D(b)(1)(B) and the IRS regulations.

An Applicant will be evaluated more favorably under this section to the extent that: (a) it or its Controlling Entity demonstrate a track record of raising investment capital; (b) it has secured investor commitments, or has a reasonable strategy for obtaining such commitments, or, if it or its Affiliates is a prior Allocatee with a track record in the past five years of raising Qualified Equity Investments and; (c) it generally demonstrates that the economic benefits of the tax credit will be passed through to a *QALICB*; and (d) it intends to invest the proceeds from the aggregate amount of its QEIs at a level that exceeds the requirements of IRC § 45D(b)(1)(B) and the IRS regulations. In the case of an Applicant proposing to raise investor funds from organizations that also will identify or originate transactions for the Applicant or from Affiliated entities, said Applicant will be evaluated more favorably to the extent that it will offer products with more favorable rates or terms than those currently offered by its investor(s) or Affiliated entities and/or will target its activities to areas of greater economic distress than those currently targeted by the investor or Affiliated entities.

6. Contacting Applicants: As a part of the substantive review process, the CDFI Fund may permit the NMTC Allocation recommendation panel member(s) to request information from Applicants for the sole purpose of obtaining, clarifying or confirming application information

or omission of information. In no event shall such contact be construed to permit an Applicant to change any element of its application. At this point in the process, an Applicant may be required to submit additional information about its application in order to assist the CDFI Fund with its final evaluation process. If the Applicant (or the Controlling Entity or any Affiliate) has previously been awarded an NMTC Allocation, the CDFI Fund may also request information on the use of those NMTC Allocations, to the extent that this information has not already been reported to the CDFI Fund. Such requests must be responded to within the time parameters set by the CDFI Fund. The selecting official(s) will make a final allocation determination based on an Applicant's file, including, without limitation, eligibility under IRC § 45D, the reviewers' scores and the amount of NMTC Allocation authority available.

7. Award Decisions: The CDFI Fund will award allocations in descending order of the final rank score, subject to Applicants meeting all other eligibility requirements; provided, however, that the CDFI Fund, in its sole discretion, reserves the right to reject an application and/or adjust award amounts as appropriate based on information obtained during the review process.

D. Allocations serving non-metropolitan counties: As provided for under Section 102(b) of the Tax Relief and Health Care Act of 2006 (Pub. L. 109-432), the CDFI Fund shall ensure that Non-Metropolitan counties receive a proportional allocation of QEIs under the NMTC Program. The CDFI Fund will endeavor to ensure that 20 percent of the *QLICs* to be made using QEI proceeds are invested in Non-Metropolitan counties. In addition, the CDFI Fund will ensure that the proportion of Allocatees that are Rural CDEs is, at a minimum, equal to the proportion of Applicants in the highly qualified pool that are Rural CDEs. A Rural CDE is one that has a track record of at least three years of direct financing experience, has dedicated at least 50 percent of its direct financing dollars to Non-Metropolitan counties over the past five years, and has committed that at least 50 percent of its NMTC financing dollars with this NMTC Allocation will be deployed in such areas. Non-Metropolitan counties are counties not contained within a Metropolitan Statistical Area, as such term is defined in OMB Bulletin No. 10-02 (Update of Statistical Area Definitions and Guidance on Their Uses) and applied using 2010 census tracts. Applicants

that meet the minimum scoring thresholds will be advanced to Phase 2 review and will be provided with “preliminary” awards, in descending order of final rank score, until the available allocation authority is fulfilled. Once these “preliminary” award amounts are determined, the CDFI Fund will then analyze the Allocatee pool to determine whether the two Non-Metropolitan proportionality objectives have been met.

The CDFI Fund will first examine the “preliminary” awards and Allocatees to determine whether the percentage of Allocatees that are Rural CDEs is, at a minimum, equal to the percentage of Applicants in the highly qualified pool that are Rural CDEs. If this objective is not achieved, the CDFI Fund will provide awards to additional Rural CDEs from the highly qualified pool, in descending order of their final rank score, until the appropriate percentage balance is achieved. In order to accommodate the additional Rural CDEs in the Allocatee pool within the available NMTC Allocation limitations, a formula reduction may be applied as uniformly as possible to the allocation amount for all Allocatees in the pool that have not committed to investing a minimum of 20 percent of their QLICIs in Non-Metropolitan counties.

The CDFI Fund will then determine whether the pool of Allocatees will, in the aggregate, invest at least 20 percent of their QLICIs (as measured by dollar amount) in Non-Metropolitan counties. The CDFI Fund will first apply the “minimum” percentage of QLICIs that Allocatees indicated in their applications would be targeted to Non-Metropolitan areas to the total NMTC Allocation award amount of each Allocatee (less whatever percentage the Allocatee indicated would be retained for non-QLICI activities), and total these figures for all Allocatees. If this aggregate total is greater than or equal to 20 percent of the QLICIs to be made by the Allocatees, then the pool is considered balanced and the CDFI Fund will proceed with the NMTC Allocation process. However, if the aggregate total is less than 20 percent of the QLICIs to be made by the Allocatees, the CDFI Fund will consider requiring any or all of the Allocatees to direct up to the “maximum” percentage of QLICIs that the Allocatees indicated would be targeted to Non-Metropolitan counties, taking into consideration their track record and ability to deploy dollars in Non-Metropolitan counties. If the CDFI Fund cannot meet the goal of 20 percent of QLICIs in Non-Metropolitan counties by requiring any or all Allocatees to commit up to the maximum percentage

of QLICIs that they indicated would be targeted to Non-Metropolitan counties, the CDFI Fund may add additional highly qualified Rural CDEs (in descending order of final rank score) to the Allocatee pool. In order to accommodate any additional Allocatees within the allocation limitations, a formula reduction will be applied as uniformly as possible, to the allocation amount for all Allocatees in the pool that have not committed to investing a minimum of 20 percent of their QLICIs in Non-Metropolitan counties.

E. Right of rejection: The CDFI Fund reserves the right to reject any NMTC Allocation Application in the case of a prior CDFI Fund award recipient, if such Applicant has failed to comply with the terms, conditions, and other requirements of the prior or existing assistance or award agreement(s) with the CDFI Fund or any other agreement under any CDFI Fund program.

The CDFI Fund reserves the right to reject any NMTC Allocation Application in the case of a prior CDFI Fund Allocatee, if such Applicant has failed to comply with the terms, conditions, and other requirements of its prior or existing Allocation Agreement(s) with the CDFI Fund.

The CDFI Fund reserves the right to reject any NMTC Allocation Application in the case of any Applicant, if an Affiliate of the Applicant has failed to meet the terms, conditions and other requirements of any prior or existing assistance agreement, award agreement, Allocation Agreement, or any other agreement under any CDFI Fund program with the CDFI Fund.

The CDFI Fund reserves the right to reject or reduce the allocation award amount of any NMTC Allocation Application in the case of a prior Allocatee, if such Applicant has failed to use its prior NMTC Allocation(s) in a manner that is generally consistent with the business strategy (including, but not limited to, the proposed product offerings, business type, fees, markets served (*i.e.* service area), and notable relationships) set forth in the Allocation Application(s) related to such prior NMTC Allocation(s) or such Applicant has been found by the IRS to have engaged in a transaction or series of transactions designed to achieve a result that is inconsistent with the purposes of IRC § 45D. The CDFI Fund also reserves the right to reject or reduce the allocation award amount of any NMTC Allocation Application in the case of an Affiliate of the Applicant that is a prior Allocatee and has failed to use its prior NMTC Allocation(s) in a manner that is generally consistent with the business strategy (including, but not limited to,

the proposed product offerings, business type, fees, markets served (*i.e.*, service area), and notable relationships) set forth in the Allocation Application(s) related to such prior NMTC Allocation(s) or has been found by the IRS to have engaged in a transaction or series of transactions designed to achieve a result that is inconsistent with the purposes of IRC § 45D.

The CDFI Fund reserves the right to reject an NMTC Allocation Application if information (including, but not limited to, administrative errors; submission of inaccurate information; or omission of information) comes to the attention of the CDFI Fund that adversely affects an Applicant's eligibility for an award, adversely affects the CDFI Fund's evaluation or scoring of an application, adversely affects the CDFI Fund's prior determinations of CDE certification, or indicates fraud or mismanagement on the part of an Applicant, its Affiliate(s), or the Controlling Entity, if such fraud or mismanagement by the Affiliate(s) or Controlling Entity would hinder the Applicant's ability to perform under the Allocation Agreement. If the CDFI Fund determines that any portion of the application is incorrect in any material respect, the CDFI Fund reserves the right, in its sole discretion, to reject the application.

The CDFI Fund reserves the right to reject any NMTC Allocation Application if additional information is obtained that, after further due diligence and in the discretion of the CDFI Fund, would hinder the Applicant's ability to effectively perform under the Allocation Agreement. In the case of Applicants (or the Controlling Entity, or Affiliates) that are regulated or receive oversight by the Federal government or a state agency (or comparable entity), the CDFI Fund may request additional information from the Applicant regarding Assurances and Certifications or other information about the ability of the Applicant to effectively perform under the Allocation Agreement. The NMTC Allocation recommendation panel or selecting official(s) reserve(s) the right to consult with and take into consideration the views of the appropriate Federal banking and other regulatory agencies. In the case of Applicants (or Affiliates of Applicants) that are also Small Business Investment Companies, Specialized Small Business Investment Companies or New Markets Venture Capital Companies, the CDFI Fund reserves the right to consult with and take into consideration the views of the Small Business Administration. An Applicant that is or is affiliated with an insured depository institution will not

be awarded an NMTC Allocation if it has a composite rating of “5” on its most recent examination, performed in accordance with the Uniform Financial Institutions Rating System.

Furthermore, the CDFI Fund will not award an NMTC Allocation to an Applicant that is an insured depository institution or is an Affiliate of an insured depository institution, if during the time period beginning with the application deadline and ending with the execution of the CY 2022 Allocation Agreement; the Applicant received any of the following:

1. CRA assessment rating of below “Satisfactory” on its most recent examination;
2. A going concern opinion on its most recent audit; or
3. A Prompt Corrective Action directive from its regulator.

The CDFI Fund reserves the right to conduct additional due diligence on all Applicants, as determined reasonable and appropriate by the CDFI Fund, in its sole discretion, related to the Applicant, Affiliates, the Applicant’s Controlling Entity and the officers, directors, owners, partners and key employees of each. This includes the right to consult with the IRS if the Applicant (or the Controlling Entity, or Affiliates) has previously been awarded an NMTC Allocation.

F. Allocation Announcement: Each Applicant will be informed of the CDFI Fund’s award decision through an electronic notification whether selected for an allocation or not selected for an allocation, which may be for reasons of application incompleteness, ineligibility, or substantive issues. Eligible Applicants that are not selected for an allocation based on substantive issues will likely be given the opportunity to receive feedback on their applications. This feedback will be provided in a format and within a timeframe to be determined by the CDFI Fund, based on available resources.

The CDFI Fund further reserves the right to change its eligibility and evaluation criteria and procedures, if the CDFI Fund deems it appropriate. If said changes materially affect the CDFI Fund’s award decisions, the CDFI Fund will provide information regarding the changes through the CDFI Fund’s website.

The CDFI Fund reserves the right, in its sole discretion, to rescind an allocation made under this NOAA, should an Allocatee be identified as ineligible due to pending or delinquent debt to the Federal government in the Do Not Pay database.

There is no right to appeal the CDFI Fund’s NMTC Allocation decisions. The

CDFI Fund’s NMTC Allocation decisions are final.

VI. Award Administration Information

A. Allocation Award Compliance:

1. Failure to meet reporting requirements: If an Allocatee, or an Affiliate of an Allocatee, is a prior CDFI Fund award recipient or Allocatee under any CDFI Fund program and is not current on the reporting requirements set forth in the previously executed assistance, allocation, or award agreement(s) or any other agreement under any CDFI Fund program as of the date the CDFI Fund provides notification of an NMTC Allocation award or thereafter, the CDFI Fund reserves the right, in its sole discretion, to reject the application, delay entering into an Allocation Agreement, and/or impose limitations on an Allocatee’s ability to issue QEIs to investors until said prior award recipient or Allocatee is current on the reporting requirements in the previously executed assistance, allocation, or award agreement(s) or any other agreement under any CDFI Fund program. Please note that the automated systems the CDFI Fund uses for receipt of reports submitted electronically typically acknowledges only a report’s receipt; such an acknowledgment does not warrant that the report received was complete and therefore met reporting requirements.

2. Pending determination of noncompliance or default: If an Allocatee is a prior award recipient or Allocatee under any CDFI Fund program and if: (i) it has demonstrated noncompliance with a previous assistance or award agreement or a default under an Allocation Agreement or any other agreement under any CDFI Fund program; and (ii) the entity has been given a timeframe to cure the noncompliance or default, the CDFI Fund reserves the right, in its sole discretion, to delay entering into an Allocation Agreement and/or to impose limitations on the Allocatee’s ability to issue QEIs to investors, during the time period given for the entity to cure the noncompliance or default and until such time as the CDFI Fund makes a final determination that the entity is in noncompliance or default, and determination of remedies, if applicable, in the sole determination of the CDFI Fund. Further, if an Affiliate of an Allocatee is a prior CDFI Fund award recipient or Allocatee and if such entity: (i) has demonstrated noncompliance under a previous assistance or award agreement or default under a previous Allocation Agreement or any other agreement under any CDFI Fund

program; and (ii) the entity has been given a timeframe to cure the noncompliance or default, the CDFI Fund reserves the right, in its sole discretion, to delay entering into an Allocation Agreement and/or to impose limitations on the Allocatee’s ability to issue QEIs to investors, during the time period given for the entity to cure the noncompliance or default and until such time as the CDFI Fund makes a final determination that the entity is in noncompliance or default, and determination of remedies, if applicable, in the sole determination of the CDFI Fund. If the prior award recipient, Allocatee or Affiliate of the Allocatee in question is unable to satisfactorily resolve the issues of noncompliance or default, in the sole determination of the CDFI Fund, the CDFI Fund reserves the right, in its sole discretion, to terminate and rescind the award notification made under this NOAA.

3. Determination of noncompliance or default status: If prior to entering into an Allocation Agreement through this NOAA, the CDFI Fund has made a final determination that an Allocatee that is a prior CDFI Fund award recipient or Allocatee under any CDFI Fund program is (i) noncompliant with a previously executed assistance or award agreement, or is in default of a previously executed Allocation Agreement or any other agreement under any CDFI Fund program; (ii) the CDFI Fund has provided written notification of such determination to such organization; and (iii) the noncompliance or default occurs during the time period beginning 12 months prior to the application deadline and ending with the execution of the CY 2022 Allocation Agreement, the CDFI Fund reserves the right, in its sole discretion, to delay entering into an Allocation Agreement and/or to impose limitations on the Allocatee’s ability to issue QEIs to investors, or to terminate and rescind the NMTC Allocation made under this NOAA.

Furthermore, if prior to entering into an Allocation Agreement through this NOAA: (i) the CDFI Fund has made a final determination that an Affiliate of an Allocatee that is a prior CDFI Fund award recipient or Allocatee under any CDFI Fund programs is in noncompliance of a previously executed assistance or award agreement or in default of a previously executed Allocation Agreement(s) or any other agreement under any CDFI Fund program; (ii) the CDFI Fund has provided written notification of such determination to such organization; and (iii) the default occurs during the time period beginning 12 months prior to the

application deadline and ending with the execution of the CY 2022 Allocation Agreement, the CDFI Fund reserves the right, in its sole discretion, to delay entering into an Allocation Agreement and/or to impose limitations on the Allocatee's ability to issue QEIs to investors, or to terminate and rescind the NMTC Allocation made under this NOAA.

B. Allocation Agreement: Each Allocatee (including their Subsidiary Allocatees) must enter into an Allocation Agreement with the CDFI Fund. The Allocation Agreement will set forth certain required terms and conditions of the NMTC Allocation which may include, but are not limited to, the following: (i) the amount of the awarded NMTC Allocation; (ii) the approved uses of the awarded NMTC Allocation (*e.g.*, loans to or equity investments in QALICBs, loans to or equity investments in other CDEs); (iii) the approved service area(s) in which the proceeds of QEIs may be used, including the dollar amount of QLICIs that must be invested in Non-Metropolitan counties; (iv) commitments to specific innovative investments discussed by the Allocatee in its Allocation Application; (v) the time period by which the Allocatee may obtain QEIs from investors; (vi) reporting requirements for the Allocatee; and (vii) a requirement to maintain certification as a CDE throughout the term of the Allocation Agreement. If an Allocatee represented in its NMTC Allocation Application that it intends to invest substantially all of the proceeds from its investors in businesses in which persons unrelated to the Allocatee hold a majority equity interest, the Allocation Agreement will contain a covenant to that effect.

In addition to entering into an Allocation Agreement, each Allocatee must furnish to the CDFI Fund an opinion from its legal counsel or a similar certification, the content of which will be further specified in the Allocation Agreement, to include, among other matters, an opinion that an Allocatee (and its Subsidiary Allocatees, if any): (i) is duly formed and in good standing in the jurisdiction in which it was formed and the jurisdiction(s) in which it operates; (ii) has the authority to enter into the Allocation Agreement and undertake the activities that are specified therein; (iii) has no pending or threatened litigation that would materially affect its ability to enter into

and carry out the activities specified in the Allocation Agreement; and (iv) is not in default of its articles of incorporation, bylaws or other organizational documents, or any agreements with the Federal government.

If an Allocatee identifies Subsidiary Allocatees, the CDFI Fund reserves the right to require an Allocatee to provide supporting documentation evidencing that it Controls such entities prior to entering into an Allocation Agreement with the Allocatee and its Subsidiary Allocatees. The CDFI Fund reserves the right, in its sole discretion, to rescind its NMTC Allocation award if the Allocatee fails to return the Allocation Agreement, signed by the authorized representative of the Allocatee, and/or provide the CDFI Fund with any other requested documentation, including an approved legal opinion, within the deadlines set by the CDFI Fund.

C. Fees: The CDFI Fund reserves the right, in accordance with applicable Federal law and, if authorized, to charge allocation reservation and/or compliance monitoring fees to all entities receiving NMTC Allocations. Prior to imposing any such fee, the CDFI Fund will publish additional information concerning the nature and amount of the fee.

D. Reporting: The CDFI Fund will collect information, on at least an annual basis from all Allocatees and/or CDEs that are recipients of QLICIs, including such audited financial statements and opinions of counsel as the CDFI Fund deems necessary or desirable, in its sole discretion. The CDFI Fund will require the Allocatee to retain information as the CDFI Fund deems necessary or desirable and shall provide such information to the CDFI Fund when requested to monitor each Allocatee's compliance with the provisions of its Allocation Agreement and to assess the impact of the NMTC Program in Low-Income Communities. The CDFI Fund may also provide such information to the IRS in a manner consistent with IRC § 6103 so that the IRS may determine, among other things, whether the Allocatee has used substantially all of the proceeds of each QEI raised through its NMTC Allocation to make QLICIs. The Allocation Agreement shall further describe the Allocatee's reporting requirements.

The CDFI Fund reserves the right, in its sole discretion, to modify these reporting requirements if it determines it to be appropriate and necessary;

however, such reporting requirements will be modified only after due notice to Allocatees.

VII. Agency Contacts

The CDFI Fund will provide programmatic and information technology support related to the Allocation Application Mondays through Fridays, between the hours of 9:00 a.m. and 5:00 p.m. ET through the last day to contact the CDFI Fund. The CDFI Fund will not respond to phone calls emails, or Service Requests in AMIS concerning the application that are received after the last day to contact the CDFI Fund. The CDFI Fund will respond to such phone calls, emails, or Service Requests in AMIS after the Allocation Application deadline in Table 1. Applications and other information regarding the CDFI Fund and its programs may be obtained from the CDFI Fund's website at <https://www.cdfifund.gov>. The CDFI Fund will post on its website responses to questions of general applicability regarding the NMTC Program.

A. Information technology support: Technical support can be obtained by calling (202) 653-0422 or by submitting a Service Request in AMIS. People who have visual or mobility impairments that prevent them from accessing the Low-Income Community maps using the CDFI Fund's website should call (202) 653-0422 for assistance. These are not toll free numbers.

B. Programmatic support: If you have any questions about the programmatic requirements of this NOAA, contact the CDFI Fund's NMTC Program Manager by submitting a Service Request in AMIS; or by telephone at (202) 653-0421. These are not toll free numbers.

C. Administrative support: If you have any questions regarding the administrative requirements of this NOAA, contact the CDFI Fund's NMTC Program Manager by submitting a Service Request in AMIS, or by telephone at (202) 653-0421. These are not toll free numbers.

D. IRS support: For questions regarding the tax aspects of the NMTC Program, contact James Holmes and Dillon Taylor, Office of the Chief Counsel (Passthroughs and Special Industries), IRS, by telephone at (202) 317-4137, or by facsimile at (855) 591-7867. These are not toll free numbers. Applicants wishing for a formal ruling request should see IRS Internal Revenue Bulletin 2020-1, issued January 4, 2020.

VIII. Information Sessions

In connection with this NOAA, the CDFI Fund may conduct one or more information sessions that will be produced in Washington, DC and broadcast over the internet via

webcasting as well as telephone conference calls. For further information on these upcoming information sessions, please visit the CDFI Fund's website at <https://www.cdfifund.gov>.

Authority: 26 U.S.C. 45D; 31 U.S.C. 321; 26 CFR 1.45D-1.

Jodie L. Harris,

Director, Community Development Financial Institutions Fund.

[FR Doc. 2022-25116 Filed 11-21-22; 8:45 am]

BILLING CODE 4810-05-P



FEDERAL REGISTER

Vol. 87

Tuesday,

No. 224

November 22, 2022

Part II

Nuclear Regulatory Commission

10 CFR Part 26

Fitness for Duty Drug Testing Requirements; Final Rule

NUCLEAR REGULATORY COMMISSION

10 CFR Part 26

[NRC–2009–0225]

RIN 3150–AI67

Fitness for Duty Drug Testing Requirements

AGENCY: Nuclear Regulatory Commission.

ACTION: Final rule and guidance; issuance.

SUMMARY: The U.S. Nuclear Regulatory Commission (NRC) is amending its regulations regarding fitness for duty (FFD) programs for certain NRC licensees and other entities to align the NRC's drug testing requirements more closely with the updates made to the U.S. Department of Health and Human Services' "Mandatory Guidelines for Federal Workplace Drug Testing Programs" in 2008 and as revised in 2017. This final rule also incorporates lessons learned from implementing the NRC's current FFD regulations. These changes enhance the ability of NRC licensees and other entities to identify individuals using illegal drugs, misusing legal drugs, or attempting to subvert the drug testing process. This final rule provides additional protections to individuals subject to drug testing and improves the clarity, organization, and flexibility of the NRC's FFD regulations. This final rule provides a new flexibility for the collection and drug testing of an oral fluid specimen as an alternative to the collection and testing of a urine specimen under direct observation conditions. The NRC also is issuing final implementation guidance for this final rule.

DATES:

Effective date: This final rule is effective December 22, 2022.

Compliance date: Compliance with this final rule is required by November 22, 2023.

ADDRESSES: Please refer to Docket ID NRC–2009–0225 when contacting the NRC about the availability of information for this action. You may obtain publicly-available information related to this action by any of the following methods:

- *Federal Rulemaking Website:* Go to <https://www.regulations.gov> and search for Docket ID NRC–2009–0225. Address questions about NRC dockets to Dawn Forder; telephone: 301–415–3407; email: Dawn.Forder@nrc.gov. For technical questions, contact the individuals listed in the **FOR FURTHER**

INFORMATION CONTACT section of this document.

- *NRC's Agencywide Documents Access and Management System (ADAMS):* You may obtain publicly available documents online in the ADAMS Public Documents collection at <https://www.nrc.gov/reading-rm/adams.html>. To begin the search, select "Begin Web-based ADAMS Search." For problems with ADAMS, please contact the NRC's Public Document Room (PDR) reference staff at 1–800–397–4209, at 301–415–4737, or by email to PDR.Resource@nrc.gov. For the convenience of the reader, instructions about obtaining materials referenced in this document are provided in the "Availability of Documents" section.

- *Attention:* You may examine and purchase copies of public documents, by appointment, at the NRC's Public Document Room (PDR), Room P1 B35, One White Flint North, 11555 Rockville Pike, Rockville, Maryland 20852. To make an appointment to visit the PDR, please send an email to PDR.Resource@nrc.gov or call 1–800–397–4209 or 301–415–4737, between 8:00 a.m. and 4:00 p.m. eastern time, Monday through Friday, except Federal holidays.

FOR FURTHER INFORMATION CONTACT: Stewart Schneider, Office of Nuclear Material Safety and Safeguards, telephone: 301–415–4123; email: Stewart.Schneider@nrc.gov; or Brian Zaleski, Office of Nuclear Security and Incident Response, telephone: 301–287–0638; email: Brian.Zaleski@nrc.gov. Both are staff of the U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001.

SUPPLEMENTARY INFORMATION:

Executive Summary

A. Need for the Regulatory Action

The U.S. Nuclear Regulatory Commission (NRC) is amending its regulations regarding fitness for duty (FFD) programs for certain NRC licensees and other entities to align the NRC's drug testing requirements more closely with U.S. Department of Health and Human Services' (HHS) "Mandatory Guidelines for Federal Workplace Drug Testing Programs" (HHS Guidelines). The HHS Guidelines govern Federal employee workplace drug testing programs at more than 100 Federal agencies and Federal agency drug testing programs (e.g., U.S. Department of Transportation) that test civilians in safety- and security-sensitive positions similar to personnel tested under the NRC's program in part 26 of title 10 of the *Code of Federal Regulations* (10 CFR), "Fitness for Duty Programs." The NRC published a

proposed rule (84 FR 48750; September 16, 2019) to align its drug testing provisions under 10 CFR part 26 more closely with HHS Guidelines published in the **Federal Register** on November 25, 2008 (73 FR 71858), effective October 1, 2010 (75 FR 22809; April 30, 2010), and to seek public input on further aligning the NRC's provisions with the HHS Guidelines published in the **Federal Register** on January 23, 2017 (82 FR 7920), effective on October 1, 2017. This final rule enhances the ability of licensees and other entities to identify individuals using illegal drugs and misusing legal drugs. This final rule also incorporates lessons learned from implementation of the 10 CFR part 26 final rule published in the **Federal Register** on March 31, 2008 (73 FR 16966; hereafter referred to as "2008 FFD final rule"). These lessons include improved methods to identify attempts to subvert the drug testing process and improvements in the clarity, consistency, and flexibility of donor protections under 10 CFR part 26. Historically, the NRC has relied upon the HHS Guidelines to establish the technical requirements for urine specimen collection, drug testing, and results evaluation and has required licensees and other entities to use HHS-certified laboratories to perform drug testing. The last NRC alignment with the HHS Guidelines was completed with the 2008 FFD final rule, which incorporated provisions from the 2004 HHS Guidelines (69 FR 19643; April 13, 2004).

B. Major Provisions

The major provisions of this final rule:

- Add initial and confirmatory drug testing for two illegal amphetamine-based controlled substances—methylenedioxymethamphetamine (MDMA) and methylenedioxyamphetamine (MDA)—referred to as "Ecstasy-type" drugs in this final rule.

- Add initial and confirmatory drug testing for four opioid drugs (hydrocodone, hydromorphone, oxycodone, and oxymorphone).

- Add initial drug testing for 6-acetylmorphine (6-AM), a metabolite of the illegal drug heroin, and update the confirmatory drug testing method for 6-AM.

- Lower the initial and confirmatory drug testing cutoff levels for amphetamine, cocaine metabolite, and methamphetamine.

- Enhance the detection of subversion attempts by strengthening the testing methods used to identify drugs and drug metabolites in urine specimens with

dilute validity test results and in specimens collected under direct observation.

- Permit the collection and drug testing of an oral fluid specimen as an alternative to the collection and testing of a directly observed urine specimen.
- Require Medical Review Officers (MROs) to evaluate the elapsed time from specimen collection to testing and exposure to high temperature, as possible causes of some invalid test results due to high solvated hydrogen ion concentration (*i.e.*, pH).
- Improve the clarity, consistency, and organization of 10 CFR part 26 by adding and updating definitions; increase flexibility by permitting additional personnel to monitor a donor that is hydrating during a shy-bladder situation; and enhance donor protections by providing additional instruction to same-gender observers used in observed collections and affording due process by requiring MROs to document the date and time that an oral request is received from a donor to initiate the retesting of a specimen.

C. Changes From the Proposed Rule to the Final Rule

In response to public comments provided on the proposed rule and in developing this final rule, the NRC has made the following changes to:

- Expand the drug testing panel to include four additional opioids (hydrocodone, hydromorphone, oxycodone, oxymorphone) listed in the 2017 HHS Guidelines.
- Provide the option to collect an oral fluid specimen as an alternative to the collection and testing of a directly observed urine specimen.
- Set a compliance deadline for this final rule of 1 year, instead of the proposed 60 days.
- Remove the proposed requirement that hydration monitors must be FFD program personnel.

D. Costs and Benefits

The NRC prepared a regulatory analysis to quantify the costs and benefits of this final rule, as well as to examine the qualitative factors to be considered in the NRC's rulemaking decision. This final rule, relative to the regulatory baseline, results in a net benefit to industry of between \$418,356, based on a 7-percent net present value, and \$692,799, based on a 3-percent net present value. This final rule results in an estimated total one-time industry cost of \$136,936, followed by a total annual industry savings of \$47,650. On a per licensee or other entity site basis, this final rule results in an average one-

time cost of \$2,321 and annual savings of \$808. Thirteen qualitative factors were evaluated in the regulatory analysis: public health (accident), occupational health (accident), offsite property, onsite property, regulatory efficiency, safeguards and security considerations, and other considerations (public perception, public trust, worker productivity, improved protection of individual rights, work environment free of drugs and the effects of such substances, safety vulnerability, and security vulnerability). The regulatory analysis includes a discussion of each qualitative factor.

The regulatory analysis results show that this rulemaking is justified because the total estimated quantified benefits exceed the estimated costs of the rule. The NRC concludes that adopting this final rule will result in an estimated increase of between 16 and 29 percent per year in the number of individuals identified as not fit for duty or trustworthy and reliable because of the use of illegal drugs, misuse of legal drugs, or an attempt to subvert the drug testing process. Based on the average number of individuals from calendar years 2009 through 2019 with a positive test result or identified as attempting to subvert a test, the estimated increase in detection each year is equivalent to identifying approximately 180 additional individuals using illegal drugs, misusing legal drugs, or attempting to subvert the drug testing process. This improved detection prevents drug-using individuals from gaining or maintaining unescorted access authorization to NRC-licensed facilities (*i.e.*, operating nuclear power reactors, nuclear power reactors under construction, and Category I fuel cycle facilities) and other locations (*e.g.*, Emergency Operations Facilities, Technical Support Centers). In addition, the enhanced detection prevents drug-using individuals from gaining or maintaining unescorted access authorization to strategic special nuclear material or sensitive information. An enhanced drug testing program may also deter drug-using individuals from seeking employment in 10 CFR part 26-regulated workplaces and incentivize those already in regulated positions to cease drug use or to seek assistance to address an addiction or misuse issue.

The regulatory analysis is available as indicated in Section XVI, "Availability of Documents," of this document.

Table of Contents

- I. Background
 - A. Health and Human Services Guidelines
 - B. History of the NRC's Fitness for Duty Program

- C. Proposed Rule and Stakeholder Outreach
- II. Discussion
 - A. The Need for Rulemaking
 1. Alignment With the Health and Human Services Guidelines
 2. Societal Drug Use
 - B. Public Comment Analysis
 - C. Description of Changes to 10 CFR Part 26
- III. Section-by-Section Analysis
- IV. Regulatory Flexibility Certification
- V. Regulatory Analysis
- VI. Backfitting and Issue Finality
- VII. Cumulative Effects of Regulation
- VIII. Plain Writing
- IX. Environmental Impact: Categorical Exclusion
- X. Paperwork Reduction Act Statement
- XI. Congressional Review Act
- XII. Criminal Penalties
- XIII. Compatibility of Agreement State Regulations
- XIV. Voluntary Consensus Standards
- XV. Availability of Guidance
- XVI. Availability of Documents

I. Background

A. Health and Human Services Guidelines

Through Executive Order 12564—Drug-Free Federal Workplace (51 FR 32889; September 17, 1986), the President of the United States designated the Department of Health and Human Services (HHS) as the Federal agency responsible for establishing and maintaining the requirements and guidance for conducting Federal employee workplace drug testing. In execution of this designation, and under the authority of Section 503 of Public Law 100–71, 5 U.S.C. Section 7301 notes, HHS developed the "Mandatory Guidelines for Federal Workplace Drug Testing Programs" (HHS Guidelines) that established a robust legal framework to conduct drug testing to provide the following: reasonable assurance of donor privacy; drug testing accuracy and precision; specimen collection, custody, and control; and results review by a Medical Review Officer (MRO).

The HHS Guidelines also established the certification requirements that each laboratory must meet to test specimens for Federal employee workplace drug testing programs. To obtain certification, a laboratory must successfully complete several rounds of performance testing and a National Laboratory Certification Program (NLCP) inspection. The certification requirements include, but are not limited to, laboratory staffing and qualifications, testing procedures, quality assurance and quality control, and results reporting. Once certified, each laboratory is subject to quarterly performance testing and NLCP inspection every 6 months to verify

adherence to the HHS Guidelines. The HHS laboratory certification process provides assurance to the U.S. Nuclear Regulatory Commission (NRC), licensees, and other entities that the testing of specimens, under part 26 of title 10 of the *Code of Federal Regulations* (10 CFR), “Fitness for Duty Programs,” is conducted with the highest standards of accuracy, precision, and quality.

Periodically, HHS updates the HHS Guidelines to enhance testing program effectiveness based on advances in drug testing technologies, processes, methodologies, and instrumentation; revises the authorized substances in the testing panel as societal drug-use trends change; and incorporates lessons learned from the NLCP. Each revision of the HHS Guidelines is published following a rigorous process that includes scientific, policy, legal, and technical review by the independent Drug Testing Advisory Board, which advises the Administrator of the HHS Substance Abuse and Mental Health Services Administration (SAMHSA); academic peer reviews; public review and comment; and input from Federal agencies that implement the HHS Guidelines. The HHS also conducts extensive outreach with affected stakeholders and researches societal drug-use trends to promulgate effective drug testing methods.

The HHS Guidelines govern the drug testing programs of over 100 Federal agencies that test Federal employees; are used by many Federal agencies that test civilians in safety- and security-sensitive positions similar to personnel tested under 10 CFR part 26, such as the U.S. Department of Transportation (DOT); and by many private entities. The NRC historically has relied on the HHS Guidelines to establish the technical requirements for urine specimen collection, specimen testing, and test result evaluation; in general, the NRC deviates from the HHS Guidelines only for considerations specific to the nuclear industry. The NRC relies on the HHS Guidelines as part of its technical basis for the drug testing requirements contained under 10 CFR part 26. Updating 10 CFR part 26 to align with changes in the HHS Guidelines ensures that the NRC’s regulations continue to be scientifically and technically sound.

B. History of the NRC’s Fitness for Duty Program

In the 1970s, the NRC and the commercial nuclear power industry began addressing concerns about the potential public health and safety impacts of fitness-for-duty (FFD)

problems at nuclear power plants. Most nuclear utilities voluntarily implemented FFD programs during the 1980s, and the NRC monitored the comprehensiveness and effectiveness of these programs. On August 4, 1986, the NRC published the “Commission Policy Statement on Fitness for Duty of Nuclear Power Plant Personnel” (51 FR 27921), which outlined the need for nuclear power plant licensees to implement programs to address FFD problems—such as illegal drug use, alcohol abuse, and misuse of legal drugs that could impair job performance. An NRC evaluation of licensee programs following the implementation of the policy statement identified a wide range in the quality and comprehensiveness of licensee FFD testing programs that ultimately resulted in the NRC’s decision to pursue rulemaking.

The NRC published a final rule, entitled “Fitness-for-Duty Programs,” in the **Federal Register** on June 7, 1989 (54 FR 24468), adding 10 CFR part 26. The 1989 FFD final rule was based on the 1988 version of the HHS Guidelines (53 FR 11970; April 11, 1988). A subsequent final rule, published in the **Federal Register** on June 3, 1993 (58 FR 31467), expanded the scope of 10 CFR part 26 to include licensees authorized to possess, use, or transport formula quantities of strategic special nuclear materials.

The NRC issued the first substantial revision to 10 CFR part 26 in a final rule on March 31, 2008 (73 FR 16966; hereafter referred to as the “2008 FFD final rule”). The 2008 FFD final rule updated the NRC’s drug testing requirements to align with the then-latest HHS Guidelines, which were issued in 2004 (69 FR 19644; April 13, 2004). The 2008 FFD final rule implemented (1) required validity testing of each specimen to address the potential for subversion of the testing process, (2) advancements in drug and alcohol testing technologies, (3) changes to drug and alcohol testing cutoff levels, and (4) lessons learned from the implementation of 10 CFR part 26 since its addition in 1989.

On November 25, 2008, HHS issued the 2008 HHS Guidelines (73 FR 71858), which included (1) an expanded drug testing panel, (2) lower drug testing cutoff levels for some substances, (3) advances in testing technologies, and (4) more detailed requirements for specimen collectors and MROs. The 2008 HHS Guidelines became effective on October 1, 2010.

On January 23, 2017, HHS issued the 2017 HHS Guidelines (82 FR 7920), which included (1) an expanded drug testing panel to include four opioid

drugs (hydrocodone, hydromorphone, oxycodone, and oxymorphone) and testing for methylenedioxyamphetamine (MDA) as an initial test analyte, (2) removal of methylenedioxyethylamphetamine (MDEA) from the drug testing panel, (3) a change to the lower pH cutoff for identifying specimens as adulterated (raised from 3 to 4), and (4) MRO requalification training and reexamination.

The 2008 and 2017 HHS Guidelines changes currently are not reflected in 10 CFR part 26.

C. Proposed Rule and Stakeholder Outreach

In June 2019, the Commission issued staff requirements memorandum (SRM)–SECY–2017–0027, “Proposed Rulemaking: Fitness-for-Duty Drug Testing Requirements (RIN 3150–AI67),” approving publication of the proposed rule. On September 16, 2019, the NRC published the proposed rule, “Fitness for Duty Drug Testing Requirements,” in the **Federal Register** (84 FR 48750). The NRC proposed to align the drug testing requirements in 10 CFR part 26 more closely with the 2008 HHS Guidelines. The proposed rule contained changes to enhance the ability of NRC licensees and other entities to identify individuals using illegal drugs or misusing legal drugs. The proposed rule also incorporated lessons learned from implementing the NRC’s current FFD regulations with regard to identifying individuals attempting to subvert the drug testing process, and provided additional protections to individuals subject to drug testing. Finally, the NRC proposed changes to improve the clarity, organization, and flexibility of the FFD regulations.

The NRC conducted significant outreach and analysis before issuing the proposed rule, including four public meetings attended by representatives of nuclear power plant licensees, the Nuclear Energy Institute, the Institute of Nuclear Power Operations, the International Brotherhood of Electrical Workers, and HHS. The proposed rule contained a thorough description of the feedback the NRC received during public meetings and how the feedback shaped the proposed rule.

The proposed rule provided a public comment period of 75 days. The NRC received 26 comment submissions on the proposed rule and draft implementation guidance, as discussed in Section II.B of this document.

During the public comment period, the NRC held a Category 3 public meeting on November 7, 2019, to

discuss with external stakeholders the proposed rule and associated draft guidance document.¹ On April 13, 2021, the NRC held an information public meeting with a question-and-answer session on the final rule implementation schedule as it pertains to the Cumulative Effects of Regulation (CER). This public meeting occurred during the development of this final rule. Summaries of both public meetings are available in the NRC's Agencywide Documents Access and Management System (ADAMS), as provided in the "Availability of Documents" section of this document. The feedback from these public meetings informed the development of this final rule.

II. Discussion

A. The Need for Rulemaking

1. Alignment With the Health and Human Services Guidelines

In the 2008 HHS Guidelines, HHS enhanced the detection of illegal drug use and the misuse of prescription drugs through the following changes: (1) lowering the initial and confirmatory testing cutoff levels for amphetamine, cocaine metabolite, and methamphetamine; (2) establishing an initial testing requirement and revising the confirmatory testing cutoff level for the heroin metabolite 6-acetylmorphine (6-AM); and (3) establishing testing for

"Ecstasy-type" drugs (which are part of the amphetamine class of drugs).

The effectiveness of the 2008 HHS Guidelines is demonstrated by the enhanced detection evident in the test results reported by HHS, DOT, and Quest Diagnostics® (Quest), which is an HHS-certified laboratory that conducts testing for both Federal workplace drug testing programs (*i.e.*, Federally-mandated) and private company testing programs (*i.e.*, U.S. general workforce). Quest annually publishes a Drug Testing Index™ report, which presents Quest laboratory testing results for Federally-mandated drug tests. On March 13, 2012, Quest reported a 33-percent increase from 2010 to 2011 in cocaine positive test results for 1.6 million Federal workplace tests conducted. Quest attributed the increase, in large part, to the lower cocaine testing cutoff levels implemented as a result of the 2008 HHS Guidelines (Quest, 2012). In the same report, Quest also noted that amphetamines positives rose by nearly 26 percent, continuing an existing upward trend, but also were "likely boosted by better detection related to the new, lower Federally-mandated cutoffs." In comparison to the 2010 positive testing rates for Federal workplace drug testing performed by Quest, the results for 2012 indicate a 12.5-percent increase in cocaine positives and a 37-percent increase in

amphetamines positives with 2013 continuing the multi-year upward trend (Quest, 2014).

An NRC analysis of annual FFD program performance reports submitted by licensees and other entities under § 26.717, "Fitness-for-duty program performance data," identified an adverse trend associated with amphetamines positive test results. The NRC report, "Summary of Fitness for Duty Performance Reports for Calendar Year 2013," identified year-over-year increases in amphetamines positive test results from 2009 through 2013. In 2009, 0.023 percent of individuals tested positive for amphetamines and by 2013, the rate increased to 0.053 percent. An NRC analysis of FFD program performance data through calendar year 2019 confirmed that the amphetamines positive test rate has continued to trend higher, with the highest rate reported at 0.095 percent of tested individuals in 2017.

Comparatively, in 2009, 0.095 percent of individuals tested positive for cocaine, with the highest rate from 2009 through 2019 reported at 0.104 percent of tested individuals in 2017. While variable by year, these positive test rates demonstrate that amphetamines and cocaine collectively account for between 23.6 percent and 28.5 percent of drug testing positives² each year, from 2015 through 2019.

TRENDS IN AMPHETAMINES AND COCAINE USE

Substance	1990	2015	2016	2017	2018	2019
Amphetamines	2.8%	9.9%	13.4%	13.6%	12.9%	12.4%
Cocaine	29.0	13.8	14.3	14.9	12.6	11.2
Total	31.8	23.7	27.7	28.5	25.5	23.6

Notes: 1. The positive testing percentages are calculated by taking the total number of positives for the particular substance and dividing that figure by the total number of positive drug test results in the year.

2. Data from 1990, the first year of 10 CFR part 26 testing, is included as the baseline for comparison.

While most of the changes in the proposed rule were made to better align 10 CFR part 26 with the 2008 HHS Guidelines, some were based on lessons learned during the implementation of the 2008 FFD final rule by licensees and other entities. In particular, the NRC proposed a number of changes to enhance the ability of licensees and other entities to identify individuals attempting to subvert the drug testing process.

Beginning in 2009, licensees and other entities had the option to use

electronic reporting forms (e-forms³) created by the NRC, in collaboration with licensees and other entities, in order to meet the annual FFD program performance reporting requirements in §§ 26.717 and 26.417(b)(2). The use of e-forms provides a uniform way of reporting detailed information on each drug and alcohol testing violation to the NRC. By 2011, over 80 percent of licensees and other entities used e-forms, with full industry adoption achieved by 2014.

The NRC report "Summary of Fitness for Duty Performance Reports for Calendar Year 2015" described a second significant trend: the prevalence of subversion attempts of the drug testing process from 2011 through 2015. In 2011, donor subversion attempts accounted for 13.7 percent of the total testing violations, or 148 of 1,080 testing violations. By 2015, subversion attempts accounted for 19.3 percent of total testing violations, or 232 of 1,200 testing violations. The prevalence of subversion attempts has continued to rise in

¹ On March 19, 2021, the NRC modified the public meeting categorization system and redefined the three categories of public meetings (86 FR 14964).

² Initial drug testing for amphetamines and confirmatory drug testing for amphetamine and methamphetamine are required by 10 CFR part 26.

³ NRC Form 890, "Single Positive Test Form;" and NRC Form 891, "Annual Reporting Form for

Drug and Alcohol Tests" can be obtained at the following NRC website: <https://www.nrc.gov/reactors/operating/ops-experience/fitness-for-duty-programs/submit-ffd-reports.html>.

subsequent years. Since 2016, subversion attempts have exceeded 20 percent of all testing violations (26.1 percent in 2016, 25.9 percent in 2017, 25.1 percent in 2018, and 28.3 percent in 2019), with the highest number of individuals identified attempting to subvert a test in 2019 at 307 individuals.

An attempt to subvert the testing process demonstrates a lack of integrity and honesty and a willful act to refuse to comply with an NRC-required drug test (see §§ 26.89(c), 26.825, “Criminal penalties,” and 50.5, “Deliberate misconduct”). Consequently, drug-using individuals present a safety vulnerability because of the potential for human performance issues due to drug use. Drug-using individuals could also present a security vulnerability because of their impairment or willful misconduct. As a result, the NRC included a number of changes in the proposed rule to enhance the ability of FFD testing programs to detect individuals attempting to subvert the drug testing process. The NRC received public input on these changes, which is discussed in Section II.B of this document.

2. Societal Drug Use

The prevalence of drug use in society is documented in the “Key Substance Use and Mental Health Indicators in the United States: Results from the 2019 National Survey on Drug Use and Health” (NSDUH), an annual survey sponsored by SAMHSA. This survey is the primary source of information on the use of illegal drugs, alcohol, and tobacco in the civilian, non-institutionalized population in the United States, ages 12 and older. The NSDUH survey estimated that in 2019, 20.8 percent of the U.S. population aged 12 or older (approximately 57.2 million Americans) used an illegal drug in the past year. The most commonly used illegal drug in 2019 was marijuana (48.2 million people), followed by the misuse of prescription pain relievers (9.7 million people). Among young adults aged 18 to 25, 39.1 percent used an illegal drug in 2019. In adults aged 26 or older, 18.3 percent used an illegal drug in 2019. Societal drug use presents a continual challenge to the fitness of the workforce relied on by licensees and other entities to perform safety and security significant duties, with the result that potential impairment and the adverse impact on human performance may affect public health and safety.

B. Public Comment Analysis

As stated in the background section, the NRC published the proposed rule and draft regulatory guide for public

comment in the **Federal Register**. The NRC received 26 comment submissions. A *comment submission* is a communication or document submitted to the NRC by an individual or entity, with one or more individual comments addressing a subject or issue. Private citizens provided 18 comment submissions, 4 licensees provided comment submissions, 2 nuclear industry organizations provided comment submissions, and 1 drug and alcohol testing association provided a comment submission.

The comment submissions were generally supportive of the regulatory action, with no comment submissions that objected to this rulemaking activity and one that did not address 10 CFR part 26. Out of the 25 remaining comment submissions, 4 comment submissions specifically noted support of the rulemaking and provided reasons related to the positive changes being proposed, enhanced efficiencies while maintaining the reliability of the FFD program, and enhanced ability to identify individuals using illegal drugs, misusing legal drugs, or attempting to subvert the drug testing process. Twenty-one comment submissions agreed to or suggested additional changes to include expanding the drug testing panel to include four additional opioids (hydrocodone, hydromorphone, oxycodone, oxymorphone) in the 2017 HHS Guidelines, providing the option to collect an oral fluid specimen for direct observation conditions, or extending the compliance deadline for this final rule. The NRC received a number of comments that were outside the scope of this rulemaking, such as comments pertaining to marijuana use and legalization. The NRC considers the public comments requesting that the NRC expand the drug testing panel to include four opioids, and to permit the collection of an oral fluid specimen for observed collection conditions to be substantive because of the resultant changes to this final rule.

The public comment submissions are available from the Federal e-Rulemaking website at <https://www.regulations.gov> under Docket ID NRC–2009–0225. The NRC prepared a summary and analysis of public comments received on the 2019 proposed rule and draft regulatory guide, as provided in the “Availability of Documents” section of this document. Responses to the public comments, including a summary of how the final rule text or guidance changed as a result of the public comments, can be found in the public comment analysis.

For more information about the associated guidance document, see the

“Availability of Guidance” section of this document.

In Section V of the Supplementary Information section for the proposed rule, the NRC sought advice and recommendations from stakeholders on the proposed rule. The NRC was particularly interested in comments and supporting rationale from the public on seven topics. The following paragraphs restate each topic and its specific request for comment, summarize comments received from stakeholders, and present the NRC’s resolution of these public comments.

1. Alignment With the HHS Guidelines

Specific Request for Comment: Two proposed changes in this rule would eliminate redundant provisions in 10 CFR part 26 that also appear in the HHS Guidelines (*i.e.*, HHS-certified laboratory personnel qualifications requirements in § 26.155, “Laboratory personnel,” and HHS-certified laboratory procedures requirements specific to the HHS Guidelines in § 26.157, “Procedures”). Because the NLCP inspection process verifies laboratory compliance with the HHS Guidelines, additional review and oversight by NRC licensees and other entities (*e.g.*, of laboratory security requirements) would be duplicative. The NRC is seeking comment on additional provisions in 10 CFR part 26 that are consistent with the HHS Guidelines and could be eliminated from 10 CFR part 26.

Commenter’s Response: One commenter agreed with the proposed changes to remove redundant provisions in 10 CFR part 26 that also appear in the HHS Guidelines, leading to duplicative oversight. In addition, the commenter recommended two new changes for consideration by the NRC. First, the commenter suggested that as long as the HHS Guidelines are followed, the NRC should remove the same-gender observed collection requirement in § 26.115, which is included in Section 4.4(b) of the HHS Guidelines. Second, the commenter stated that the NRC should eliminate the redundant requirements for MRO specimen handling in 10 CFR part 26.

NRC Response: The NRC disagrees. The NRC acknowledges that the HHS Guidelines contain similar provisions regarding the same-gender collector requirement in § 26.115(e) and the MRO specimen handling requirements in 10 CFR part 26. However, NRC licensees and other entities are subject to the requirements in 10 CFR part 26 but are not required to comply with the HHS Guidelines. Because removing these requirements from 10 CFR part 26

would completely eliminate these requirements for NRC licensees and other entities, the NRC will not remove these requirements. No changes were made to this final rule as a result of this comment.

Commenter's Response: One commenter recommended that the NRC establish a streamlined process other than rulemaking for nuclear facilities to adopt future HHS Guidelines upon issuance.

NRC Response: The NRC disagrees. Streamlining the process to revise 10 CFR part 26 whenever the HHS Guidelines change is outside the scope of this rulemaking. No changes were made to this final rule as a result of this comment.

2. Special Analyses Testing

Specific Request for Comment: The proposed rule includes new requirements in § 26.163(a)(2) for the special analyses testing of urine specimens for drugs and drug metabolites. The first would require special analyses testing of specimens with dilute validity test results when initial drug testing identifies a drug or drug metabolite within 40 percent of the testing cutoff level. Currently, special analyses testing of dilute specimens is optional. The second new requirement would expand special analyses testing to specimens collected under direct observation as required by § 26.115(a)(1) through (3) and new paragraph (a)(5). The NRC is seeking comment on whether special analyses testing should also apply to the testing of individuals that already have tested positive on a 10 CFR part 26 test (*i.e.*, denied unescorted access authorization by § 26.75(d) for a first or second drug testing positive result). Requiring special analyses testing in this case would add a level of assurance to follow-up testing required by § 26.69(b)(6), which is conducted to confirm continued abstinence from illegal drug use and/or the misuse of legal drugs.

Commenter's Response: One commenter supported applying special analyses testing for individuals that have already tested positive and indicated that it should be performed after the immunoassay and gas chromatography/mass spectrometry (GC/MS) confirmation tests. The commenter suggested that special analyses testing would identify new drugs used and provide trends in drug use by different business departments and employee levels.

NRC Response: The NRC disagrees. The reasons the commenter provided for recommending that special analyses testing be applied to the testing of

specimens collected from individuals with a prior drug testing positive result do not apply as follows:

(1) Special analyses testing would not identify new drugs; it would only identify the drugs in the drug testing panel used by the licensee or other entity.

(2) Special analyses testing would not provide additional transparency regarding the departments or employee levels where drug use is identified. The NRC already collects information in the annual FFD program performance reports that licensees and other entities submit to the NRC under §§ 26.717 and 26.417(b)(2). Performance reports provide the employment type (*i.e.*, licensee employee, contractor/vendor) and labor category (*e.g.*, supervisor, reactor operator, security) of each individual with a positive test result.

Special analyses testing lowers the initial (*i.e.*, immunoassay) and confirmatory (*i.e.*, GC/MS) testing cutoff levels for existing substances in the drug testing panel used by the licensee or other entity. Lower testing cutoff levels increase the timeframe of detection after use of a drug, thereby increasing the likelihood of detecting drug use. Accordingly, no changes were made to this final rule as a result of this comment.

Commenter's Response: One commenter stated that if an individual had already tested positive, direct observation testing would be unnecessary because the individual had already tested positive. The commenter supported using special analyses testing for retesting a specimen.

NRC Response: The NRC disagrees. As described in the proposed rule, the NRC would expand special analyses testing to specimens collected under direct observation as required by § 26.115(a)(1) through (3) and a new paragraph (a)(5). Specimens collected under the conditions described in § 26.115(a)(1) through (3) and (a)(5) would not have already tested positive, as stated by the commenter. Instead, the specimens subject to special analyses testing would be collected under direct observation for the following reasons:

- The donor presents a specimen reported by an HHS-certified laboratory as adulterated, substituted, or invalid, and the MRO determines that no adequate medical explanation exists for the result and that another specimen should be collected from the donor;
- The donor provides a specimen that falls outside of the acceptable temperature range specified in § 26.111(a);
- Donor conduct during the collection process indicates an attempt

to dilute, substitute, or adulterate the specimen; or

- The MRO verifies that a specimen is positive, adulterated, or substituted; the donor requests that a retest of the specimen be performed at a second HHS-certified laboratory; but the specimen is not available for testing.

Accordingly, no changes were made to this final rule in response to this comment.

Commenter's Response: One commenter stated that if an individual reported a problem with illegal drug use, random drug testing should be directly observed, and special analyses testing performed on the specimens collected.

NRC Response: The NRC disagrees. This comment is beyond the scope of this rulemaking because the proposed rule did not include any changes to the exclusive grounds for performing a directly observed collection in § 26.115. As described below, appropriate mechanisms currently exist within 10 CFR part 26 to address a situation where an individual self-reports an illegal drug use problem to the licensee or other entity.

The commenter's scenario most likely would apply to an individual that already had been granted unescorted access (UA) or unescorted access authorization (UAA) by a licensee. In this instance, if the individual was an employee of the licensee, they could utilize the Employee Assistance Program (EAP) that each FFD program must offer under § 26.35. The EAP is designed to achieve early intervention and provide for confidential assistance. If the individual self-refers for assistance to the EAP, then the EAP is required to protect the identity and privacy of the individual except if the individual waives the right to privacy or the individual's condition or actions pose or have posed an immediate hazard to himself or herself or others.

If, however, the individual self-reports a problem outside the EAP, then the licensee or other entity would be required to disposition the situation under § 26.69(d), "Maintaining authorization with other potentially disqualifying FFD information." The definition of "potentially disqualifying FFD information" in § 26.5 includes that an individual has used illegal drugs. The licensee or other entity also may consider conducting for-cause testing under § 26.31(c)(2) based on receiving credible information that the individual is engaging in substance abuse. If on the other hand, the individual had not been granted UA or UAA by the licensee, but had already provided a specimen for pre-access testing required under

§ 26.65, “Pre-access drug and alcohol testing,” or § 26.69, “Authorization with potentially disqualifying fitness-for-duty information,” and therefore would be subject to random testing, then the licensee would be required to evaluate the individual’s disclosure under § 26.69(c), “Granting authorization with other potentially disqualifying FFD information.”

The NRC did not propose changes to special analyses testing criteria for random tests, however, a licensee or other entity may use lower testing cutoff levels for any condition for testing if they meet the requirements in § 26.31(d)(3)(iii). Accordingly, no changes were made to this final rule in response to this comment.

Commenter’s Response: One commenter indicated that special analyses testing will not provide additional value for random and follow-up testing and asserted that special analyses testing would make it difficult to credit random tests for follow-up tests. However, it is reasonable to conduct special analyses testing for the first observed test.

NRC Response: The NRC disagrees, in part. The NRC sought comment on whether special analyses testing should also apply to follow-up tests conducted on individuals that previously tested positive on a 10 CFR part 26 test and to whom a licensee or other entity subsequently granted unescorted access authorization. Special analyses testing would provide additional value for follow-up tests because it lowers the testing cutoff levels for the substances in the drug testing panel used by the licensee or other entity. Use of lower testing cutoff levels increases the timeframe of detection after use of a drug, thereby increasing the likelihood of detecting drug use.

However, the NRC agrees that because random tests would not be subject to the lower cutoff levels used in special analyses testing, the licensee or other entity could not take credit for a random test to meet the follow-up testing requirement (*i.e.*, count a random test as meeting a follow-up testing requirement), as currently permitted in § 26.69(b)(6).

The NRC did not propose nor request comment on whether an individual with a first or second confirmed positive drug test result under 10 CFR part 26 should be subject to special analyses testing for the pre-access test conducted under § 26.69(b). As a result, this comment is beyond the scope of this rulemaking. Accordingly, no changes were made to this final rule in response to this comment.

3. Provide Flexibility To Conduct Additional Specimen Validity Tests

Specific Request for Comment: Section 26.31(d)(1)(i)(D) permits a licensee or other entity to utilize lower cutoff levels and drug testing assays without forensic toxicologist review if the HHS Guidelines are revised to authorize use of the assay and testing cutoff levels. However, § 26.161(h) prohibits licensees and other entities from using more stringent cutoff levels for validity tests. The NRC is seeking comment on whether § 26.161(h) should be revised to provide a licensee or other entity with the option to conduct additional specimen validity tests and/or to utilize lower cutoff levels if the HHS Guidelines are revised in the future to include such testing.

Commenters’ Response: Two commenters addressed the issue to provide flexibility to conduct additional specimen validity testing. The first commenter supported providing licensees and other entities with the option to use lower cutoff levels to conduct specimen validity testing. The commenter suggested that licensees and other entities have the flexibility to use different forms of testing such as hair testing. In this case, “the integrity and accountability of the program should be within NLCP Audit parameters. This must be checked and accounted for so there is not mis-representation at any level.”

The second commenter stated that providing the option to conduct additional specimen validity tests may result in an inconsistent approach across the industry and preferred a streamlined approach to adopt future updates to the HHS Guidelines.

NRC Response: The NRC agrees, in part. Licensees and other entities should be provided with the option to utilize lower cutoff levels for existing specimen validity tests performed under 10 CFR part 26, as long as those cutoff levels are consistent with the current HHS Guidelines. Affording licensees and other entities with the flexibility to use lower cutoff levels to perform validity testing is consistent with the testing principle that the NRC established in § 26.31(d)(1)(i)(D) for drug testing. Section 26.31(d)(1)(i)(D) permits a licensee or other entity to use lower cutoff levels to test for drugs specified in 10 CFR part 26 and does not require the review of the cutoff levels by a forensic toxicologist if the cutoff levels are consistent with the current HHS Guidelines. Providing a licensee or other entity with flexibility to adopt improvements in the existing validity tests performed under 10 CFR part 26 is

consistent with a key goal of this rulemaking: enhance the methods for detecting subversion attempts. The NRC acknowledges that providing the option to use lower cutoff levels for existing validity tests may result in variability among some licensees and other entities in the performance of such tests, but this approach is consistent with existing practice for drug testing and was consistent with the optional use of special analyses testing under § 26.163(a)(2) until this final rule mandated such testing.

Accordingly, § 26.161(h) in this final rule has been revised to read, “*Validity test cutoff levels.* Licensees and other entities may use more stringent cutoff levels for validity tests than those specified in this section only if the testing is performed at an HHS-certified laboratory.” The NRC disagrees that flexibility should be provided to collect and test specimens other than urine as an acceptable alternative to the current validity tests performed under 10 CFR part 26. This comment is beyond the scope of this rulemaking.

4. Effective Date of the Final Rule

Specific Request for Comment: If the proposed rule is finalized, the NRC anticipates providing a 60-day implementation period from the date that the final rule is published in the **Federal Register**. The effective date of the final rule and the compliance date for licensees and other entities would be 60 days after the date that the final rule is published in the **Federal Register**. The NRC is seeking comment on whether this implementation time period is appropriate based on the proposed rule changes.

Commenters’ Response: Two commenters disagreed with the proposed effective date of 60 days after the publication date of the final rule. The first commenter argued that the proposed 60-day timeframe did not provide sufficient time to understand the new requirements and completely communicate them to all departments and sections. The commenter recommended at least 120 days and noted that this timeframe is still very aggressive.

The second commenter stated that licensees will need approximately 12 months to fully and effectively implement the new program utilizing established procedures. The commenter explained that once the rule is issued, licensees will need to “evaluate change management plan items to include procedures, union/lab contracts, computer systems, and training.”

The second commenter also recommended that the NRC clarify that

during the transition period, any program may accept and rely on another program's FFD-related information as long as the information being shared is compliant with the sharing program's current 10 CFR part 26 processes.

NRC Response: The information provided by the two commenters was insufficient to support a change to the proposed 60-day implementation timeframe to comply with the final rule changes. However, the public provided substantive information during the April 13, 2021, public meeting on the CER for this rule to justify additional implementation time. Specifically, an industry stakeholder stated that an implementation timeframe of 1 year was more appropriate than 60 days because of operational challenges posed to a licensee's FFD program staff before, during, and after Spring (February to May) and Fall (August to November) refueling outages at operating nuclear power reactors. The licensees of some power reactor sites also impose training and system change blackout periods 2 months before, during, and 2 months after reactor outages. This industry stakeholder also described additional challenges in meeting the 60-day implementation timeframe due to updates to the FFD training system used by the industry, licensee information technology system changes, and the ongoing impacts of the Coronavirus Disease 2019 pandemic such as the remote work status of some staff. A summary of this meeting is available, as provided in the "Availability of Documents" section of this document. Three comment submissions received after the public comment period closed affirmed the stakeholder feedback presented at the CER public meeting on the implementation timeframe.

Accordingly, the compliance deadline was revised to be 1 year from the date that this final rule is published in the **Federal Register**. Because licensees and other entities can implement the new requirements before the 1-year deadline, licensees and other entities that do so should inform the NRC of their implementation date through their 10 CFR 26.717 annual FFD program performance reports.

The NRC disagrees with the second commenter's request to clarify that during the implementation period of the final rule, any program may accept and rely on another program's FFD-related information as long as the information being shared is compliant with the sharing program's current 10 CFR part 26 processes. No change is necessary because the existing requirements in 10 CFR part 26 permit the sharing of information. For example, to grant

authorization, licensees and other entities shall ensure that a suitable inquiry has been conducted under § 26.63, "Suitable inquiry," to verify an individual's self-disclosed information and to determine whether any potentially disqualifying FFD information is available. A suitable inquiry can involve licensees sharing information about an individual collected under 10 CFR part 26. Accordingly, no changes were made to this final rule as a result of this request.

5. Direct Observation of Specimen Collection

Specific Request for Comment: The proposed rule retains the requirement for direct observation during the collection of a second sample when there are indications of a subversion attempt during the initial collection. The NRC is seeking comment on whether there are any effective alternatives to direct observation that will assist in preventing subversion of the drug testing process.

Commenters' Response: One commenter responded that a direct observation collection is the only way to ensure the integrity of the specimen collected from the donor and that there were no effective alternatives. The commenter further stated that the highest integrity of the procedure must be maintained between the observer and donor (*i.e.*, no conflicts of interest, no harassment, and no bribery).

Another commenter offered that an oral fluid specimen collection is an effective alternative to collecting a urine specimen under direct observation. The commenter also suggested that an oral fluid specimen should be considered if a donor is unable to provide the minimum quantity of urine on the initial attempt and that 10 CFR part 26 should state that industry can adopt and implement the HHS Guidelines for oral fluid testing within their programs without submitting exemptions or awaiting rulemaking.

NRC Response: The NRC agrees that collecting an oral fluid specimen under direct observation of the specimen collector is equivalent to and equally effective as collecting a urine specimen from a donor under the observed collection conditions in § 26.115(a)(1) through (3) and a new paragraph (a)(5). The NRC's basis for this decision is the HHS issuance of the "Mandatory Guidelines for Federal Workplace Drug Testing Program-Oral/Fluid" (2019 HHS OF Guidelines) on October 25, 2019 (84 FR 57554). The 2019 HHS OF Guidelines became effective on January 1, 2020. The 2019 HHS OF Guidelines relied on the technical basis of the

acceptability of oral fluid as an alternative specimen in the Federal employee workplace drug testing program that was presented in the proposed revisions to the HHS Guidelines published on May 15, 2015 (80 FR 28101).

Under the conditions permitted in this final rule, the testing of an oral fluid specimen is equally effective in identifying the same substances tested in urine. Oral fluid is tested at an HHS-certified laboratory, with the same HHS inspection and oversight process used for urine specimen testing laboratories.

Although the NRC is permitting a licensee or other entity to collect a urine or oral fluid specimen under specified direct observation conditions, each specimen chosen has advantages and disadvantages. The intent of the flexibility offered by the changes in this final rule is to provide the licensee or other entity with the ability to collect and test the appropriate specimen for the collection condition encountered. The following discussion describes how both collection methods can detect attempts to subvert the testing process.

- Urine specimen collections are valuable in identifying subversion attempts. Collecting a urine specimen under direct observation requires the donor, in the presence of a same-gender observer, to remove his or her clothing between the waist and the knees. This clothing removal process has revealed cheating paraphernalia, definitive proof of a donor's attempt to subvert the testing process. An NRC analysis of FFD program performance data submitted to the NRC under §§ 26.717 and 26.417(b)(2) determined that the two most likely subversion determination scenarios are either a donor refuses to provide a second urine specimen under direct observation, or the donor's second observed urine specimen tests positive for a drug and the donor's initial unobserved urine specimen tests negative for that drug. The collection and testing of a donor's two urine specimens, the first unobserved and second observed, also provide the MRO with contemporaneous information on the physical characteristics of the specimens that can be used to inform a subversion determination. For example, in rare instances when both the unobserved and observed specimens provided by a donor test negative for drugs, the MRO's comparison of the physical characteristics of the two specimens has identified medically impossible differences in specimen temperature, pH, creatinine, and specific gravity test results that have resulted in subversion determinations. The existing observed urine collection

process has proven effective in identifying subversion attempts and urine drug testing has been successfully conducted by licensees and other entities under 10 CFR part 26 since 1990.

- Oral fluid specimen collections would not be expected to identify subversion attempts. Collecting an oral fluid specimen is always performed under the direct observation of the collector and does not require a same-gender collector (*i.e.*, the donor does not remove his or her clothing from the waist to the knees). It is possible that a donor could retain cheating paraphernalia used during the provision of the initial unobserved urine specimen because clothing is not removed. If the licensee or other entity suspects that a donor may be in possession of subversion paraphernalia, then the licensee or other entity can consider taking additional action to identify the paraphernalia before collecting an oral fluid specimen. In the absence of any identifiable subversion paraphernalia, the licensee or other entity could then conduct an oral fluid specimen collection to meet an observed collection requirement.

The window of detection for drugs and drug metabolites in urine is somewhat longer than in oral fluid. However, this difference is immaterial under the conditions that oral fluid testing is permitted in this final rule. Oral fluid drug testing is permitted for collection conditions warranted by information suggesting a possible subversion attempt. Individuals that attempt to subvert the drug testing process do so because of recent use of one or more of the substances included in the drug-testing panel used by the licensee or other entity. It is unlikely that a donor would risk a permanent denial of unescorted access under § 26.75, “Sanctions,” for an identified subversion attempt unless they likely would test positive on drug testing. As a result, the NRC believes that oral fluid and urine specimen testing likely would be equally effective in identifying recent drug use. It is notable that identifying any given substance through drug testing is dependent on the chemical properties of the substance, the retention of that particular substance in the human body, frequency of use, and the genetic makeup of the user, which impacts drug metabolism rates. These complexities apply to urine and oral fluid specimen testing.

Another difference between urine and oral fluid drug testing is the volume of the biological specimen needed for testing. An oral fluid specimen collection device must obtain a

minimum of 1 milliliter (mL), whereas urine drug testing requires a volume of 30 to 45 mL. This volume difference must be taken into account by licensees and other entities choosing to use oral fluid testing because sufficient specimen volume must be available to support retesting of a specimen should a donor request specimen retesting following a positive test result under § 26.165.

The oral fluid collection process requires fewer steps to complete, and therefore may take less time to complete than for a urine specimen. The stability of oral fluid specimens also may be better than urine specimens because oral fluid specimen collection devices contain a stability buffer, which may reduce the necessity for refrigeration under certain collection and specimen handling conditions.

For each of the directly observed collection conditions in § 26.115(a)(1) through (3) and a new paragraph (a)(5), a licensee or other entity must always collect either urine or oral fluid specimens. For example, a licensee could continue to collect a urine specimen under every § 26.115(a)(2) directly observed collection condition when the initial urine specimen provided is outside the acceptable temperature range, but could choose to collect an oral fluid specimen under every § 26.115(a)(1) directly observed collection condition after an invalid urine specimen test result without a legitimate medical explanation. The required special analyses testing provisions included in this final rule under § 26.163(a)(2) apply to the specimens collected under direct observation regardless of the specimen that is tested (*i.e.*, both for urine and oral fluid).

As a result of including oral fluid specimen collection and testing under specified direct observation conditions in this final rule, the NRC is making the changes discussed in Section II.C of this document, under “Acceptable Specimens for Observed Collection.”

The commenter’s request to revise 10 CFR part 26 to permit the collection of an oral fluid specimen in the instance where a donor is unable to provide the minimum quantity of urine on the initial collection attempt (*i.e.*, a shy bladder) is beyond the scope of this rulemaking because the NRC did not propose, nor request comment on, the use of oral fluid specimens when a donor is unable to provide the minimum quantity of urine on the initial collection attempt.

6. 2017 HHS Guidelines—New Test Analytes

Specific Request for Comment: On January 23, 2017, HHS issued its latest revision of the Mandatory Guidelines for Federal Workplace Drug Testing Programs Using Urine Specimens (82 FR 7920). Subpart C, “Urine Drug and Specimen Validity Tests,” of the 2017 HHS Guidelines was revised to include additional initial and confirmatory test analytes for certain opioids; specifically, hydrocodone, hydromorphone, oxycodone, and oxymorphone. The NRC is seeking comment on whether §§ 26.31(d)(1) and 26.405(d) should be revised to identify hydrocodone, hydromorphone, oxycodone, and oxymorphone test substances, and whether §§ 26.133 and 26.163(a)(1) and (b)(1) should be revised to require initial and confirmatory testing of these drugs at the cutoff levels recommended in the 2017 HHS Guidelines.

Commenters’ Response: Three commenters expressed support for expanding the 10 CFR part 26 drug testing panel to include the four opioids added to the 2017 HHS Guidelines (*i.e.*, hydrocodone, hydromorphone, oxycodone, and oxymorphone). One commenter stated that adopting this expanded drug testing panel will provide greater reassurances that persons with authorization to access licensed facilities are fit for duty. Another commenter expressly endorsed the cutoff levels recommended in the 2017 HHS Guidelines for these drugs.

NRC Response: The NRC agrees. The NRC evaluated detection changes following implementation of drug testing under the 2017 HHS Guidelines on safety-sensitive worker populations analogous to the individuals subject to 10 CFR part 26. The U.S. Department of Transportation (DOT) began drug testing under the 2017 HHS Guidelines on January 1, 2018 (82 FR 52229; November 13, 2017). The NRC assessment of DOT test results data for 2018 identified a significant increase in the number of testing violations for opioid positive test results. The NRC analyzed drug testing data from the three modal administrations most comparable to the population tested under 10 CFR part 26 (Federal Aviation Administration (FAA), Federal Rail Administration (FRA), and Federal Transit Administration (FTA)). The opioid positive testing violation rate for FAA increased from 0.0196 percent in 2017 to 0.0652 percent in 2018 (233-percent increase), for FRA from 0.0322 percent in 2017 to 0.0904 percent in 2018 (181-percent increase), and for FTA from 0.0349 percent in 2017 to

0.1623 percent in 2018 (365-percent increase). These increases in testing violations demonstrated both the effectiveness of the 2017 HHS Guidelines expanded opioid testing panel and also the prevalence of illicit use of these substances in analogous worker populations to those tested under 10 CFR part 26.

Most FFD programs already require individuals to report the use of any substance (e.g., prescription drug, over-the-counter substance) with product labeling or use information indicating a potential impairing impact on performance, whereby an assessment would be conducted by the MRO to ensure that the individual can safely perform assigned job activities. Required testing for the four additional opioids in the 2017 HHS Guidelines also will likely increase the level of compliance in reporting the use of these impairing substances to the FFD program consistent with the FFD program prescription drug policy. This change is likely because of the uniform testing for these substances, as well as the consequence for identifying individuals violating the FFD policy and the minimum sanctions that apply under § 26.75 for positive test results.

Accordingly, the NRC revised §§ 26.31(d)(1), 26.133, 26.163(a)(1) and (b)(1), 26.169(h)(3), 26.185(j), and 26.405(d) in this final rule to align with the 2017 HHS Guidelines by adding testing for hydrocodone, hydromorphone, oxycodone, and oxymorphone.

Commenter's Response: One commenter expressed concern with the increasing number of individuals being placed into follow-up testing programs as a result of the opioid epidemic. The commenter asserted that a select few of the nuclear facilities have expanded their panels to address the opioid crisis. The commenter also stated that these facilities place individuals into the follow-up program for the purpose of monitoring abstinence from opiate addiction: "However, when the individual in the follow up program travels to another utility; they are not monitored for the substance for which they were placed in the follow-up program; as these programs have not expanded the panel and have no provision to test for the abused opiate." Therefore, the commenter declared that "industry is currently ill equipped to monitor the problem because of the significant gap in the follow-up program's ability to detect on going opiate abuse."

The commenter recommended that the rule include language that addresses the opiate epidemic and includes

provisions for collection and testing under every FFD test condition.

NRC Response: The NRC agrees. See the previous NRC response.

7. Methylenedioxyethylamphetamine

Specific Request for Comment: The 2008 HHS Guidelines adds methylenedioxyethylamphetamine (MDEA) as a confirmatory analyte to the drug testing panel in Section 3.4. However, when the HHS revised the mandatory guidelines in 2017, HHS removed MDEA from Section 3.4 stating that "[t]he Department has evaluated the comments and has removed MDEA from the Guidelines (i.e., MDEA is no longer included as an authorized drug in Section 3.4). The number of positive MDEA specimens reported by HHS-certified laboratories (i.e., information provided to the Department through the NLCP) does not support testing all specimens for MDEA in Federal workplace drug testing programs" (82 FR 7920, 7923; January 23, 2017). The NRC is not proposing to adopt the 2008 HHS Guidelines' addition of MDEA as a confirmatory test analyte at this time. As a result, the NRC is also proposing to add MDA to the initial testing panel to fully align with the "Ecstasy drugs" testing panel in the 2017 guidelines. The NRC is seeking comment on these changes.

Commenters' Response: Two commenters responded to the specific request for comment on whether MDEA and MDA testing is needed. The first commenter disagreed that the NRC should not include MDEA in the drug testing panel, and stated that not testing for this substance would provide an opportunity for drug use in a sensitive position.

The second commenter favored aligning with the 2017 HHS Guidelines, which does not include MDEA, even though "Ecstasy drugs" have not been a prevalent issue in the industry. However, the commenter recommended that if blind specimen testing remains a requirement, then NRC should consider eliminating the testing of drugs that are not prevalent issues in the industry.

NRC Response: The NRC disagrees, in part. The 2017 HHS Guidelines established the appropriate minimum testing standard for the drugs and drug metabolites to be tested in the specimens collected from individuals subject to testing under 10 CFR part 26. The 2017 HHS Guidelines (82 FR 7923) stated that HHS "understands that MDA and some other analytes also have a low incidence, but believes that continued testing for these analytes is warranted in a deterrent program. In particular, inclusion of MDA as an initial and

confirmatory test analyte is warranted because, in addition to being a drug of abuse, it is a metabolite of MDEA and MDMA." The NRC agrees with this HHS position.

Further, § 26.31(d)(2) provides flexibility to licensees and other entities to consult with local law enforcement authorities, hospitals, and drug counseling services to determine whether other drugs with abuse potential are being used in the geographical locale of the facility and by the local workforce that may not be detected in the standard testing panel under § 26.31(d)(1). When appropriate, a licensee or other entity may add other drugs to the testing panel, but only if the additional drugs are listed in Schedules I through V of section 202 of the Controlled Substances Act [21 U.S.C. 812]. MDEA is a Schedule I substance. The licensee or other entity must also inform the NRC under 10 CFR 26.717(b)(2) that it is testing for the additional drugs. The NRC has not received information from any licensee or other entity that testing for Ecstasy-type drugs has been performed under a 10 CFR part 26 testing program. Therefore, no basis exists to evaluate the commenter's position regarding the prevalence of Ecstasy-type drugs in the industry, but changes in substance abuse trends do occur over time and testing for substances in the amphetamines drug class supports a deterrent testing program.

The commenter's requested change to the blind performance test sample requirements in § 26.168 is beyond the scope of this rulemaking because the NRC did not propose changes to, nor request comment on, the blind performance test sample requirements.

Accordingly, the NRC did not change this final rule in response to these comments.

C. Description of Changes to 10 CFR Part 26

Definitions

This final rule adds seven new definitions and revises seven existing definitions under § 26.5, "Definitions." The revisions and additions improve consistency with Section 1.5 of the 2008 HHS Guidelines and improve the clarity, consistency, and accuracy of the requirements under 10 CFR part 26. Specifically, this final rule adds definitions for: *Cancelled test*, *Carryover*, *Certifying Scientist*, *Federal custody and control form*, *Lot*, *Rejected for testing*, and *Responsible Person*. This final rule also revises the definitions for: *Calibrator*, *Control*, *Dilute specimen*, *HHS-certified laboratory*, *Invalid result*,

Limit of quantitation, and Substituted specimen.

Cancelled test. The MRO will cancel the testing of a donor's urine specimen and report that action to the licensee or other entity after the testing laboratory (*i.e.*, licensee testing facility (LTF) or HHS-certified laboratory) reports that the specimen was rejected for testing or the donor requested additional testing of a specimen at a second HHS-certified laboratory under § 26.165(b) and the specimen was not available for testing due to circumstances outside of the donor's control (*e.g.*, specimen is lost in transit). Sections 26.129(b)(2) and 26.159(b)(2) describe the only circumstances requiring an MRO to "cancel the testing of a donor's urine specimen." However, §§ 26.129(b)(2) and 26.159(b)(2) do not use the term *cancelled test*, nor is the term defined under § 26.5. Adding the definition for *cancelled test* and updating §§ 26.129(b)(2) and 26.159(b)(2) to specifically use that term clarifies the actions taken by an MRO and improves consistency between 10 CFR part 26 and the 2008 and 2017 HHS Guidelines. The NRC is also adding the term *cancelled test* to § 26.165(f)(1) and (f)(2) to clarify the actions taken by an MRO when a specimen is rejected for testing by the laboratory and the MRO cancels the testing of the specimen. For completeness, a *cancelled test* for alcohol breath testing is also defined. The definition presented by the NRC staff at the October 11, 2011, public meeting only described cancelled test results associated with urine testing. For alcohol testing only, *cancelled test* means a test result that was not acceptable because testing did not meet the quality assurance and quality control requirements in § 26.91, "Acceptable devices for conducting initial and confirmatory test for alcohol and methods of use."

Carryover. This final rule adds a definition for *carryover* to § 26.5. *Carryover* is the effect that occurs when a test result for a donor's specimen or quality control sample has been affected by a preceding specimen tested on the same analytical instrument. For example, if the concentration of a drug in one donor specimen was not completely eliminated from the analytical instrument before the next donor specimen is tested, the residual drug concentration in the instrument may contribute to a false positive test result for the next donor specimen tested. *Carryover* also applies to donor specimens containing an adulterant or interfering substance. The term *carryover* is not currently defined under § 26.5. However, the term *carryover* is

used in §§ 26.137(e)(7) and 26.167(a), which require LTFs and HHS-certified laboratories to ensure that *carryover* does not contaminate the testing of a donor's specimen or otherwise affect a donor's specimen results. In addition, § 26.91(c)(5) describes the requirement to ensure that *carryover* does not affect alcohol testing results when using evidential breath testing devices. The NRC's definition is similar to the definition in Section 1.5 of the 2008 and 2017 HHS Guidelines but does not include the phrase "(*e.g.*, drug concentration)" because *carryover* applies also to validity testing (*e.g.*, adulterants, interfering substances) and alcohol testing.

Certifying Scientist. This final rule adds a definition for *Certifying Scientist* to § 26.5. The position title is used in § 26.169(a) and (g) but is not currently defined. A *Certifying Scientist* is defined as the individual at the HHS-certified laboratory responsible for verifying the chain of custody and scientific reliability of any test result reported by the HHS-certified laboratory. Adding this definition from the HHS Guidelines improves consistency between 10 CFR part 26 and the 2008 and 2017 HHS Guidelines and the clarity of 10 CFR part 26. A conforming change is made to § 26.169(a) to capitalize the position title in the phrase "the laboratory's certifying scientist."

Federal custody and control form (Federal CCF). This final rule adds a definition for the term *Federal custody and control form (Federal CCF)* to § 26.5. The Federal CCF is defined as any HHS-approved form, which has not expired, that is published in the **Federal Register** and is used to document the collection, custody, transport, and testing of a specimen. Including this definition more closely aligns 10 CFR part 26 with Section 1.5 of the 2008 and 2017 HHS Guidelines and improves the clarity of the rule by defining the term, which is already used in § 26.153(g). The NRC is using the generic title, *Federal CCF*, to avoid the need for future regulatory changes, should the title of the form change. The definition also provides flexibility in accounting for additional forms that SAMHSA may create for use when conducting drug testing of alternative specimens (*e.g.*, hair). To align with the new definition, "Federal custody-and-control form" is replaced with the term "*Federal CCF*" in § 26.153(g). In addition, to improve the consistency of terminology used throughout 10 CFR part 26, this final rule replaces the term "custody and control form" with the term "*Federal CCF*." The plural versions, "custody and control forms" and "custody and

control form(s)," are also replaced with the terms "Federal CCFs" and "Federal CCF(s)," respectively. Finally, this final rule corrects inconsistencies where "custody-and-control" form or forms were used incorrectly and instead should have referred to "chain-of-custody" form or forms.

The NRC's regulations under 10 CFR part 26 do not preclude the use of electronic versions of the Federal CCF or the use of licensee or other entity-developed forms, consistent with existing requirements in § 26.153(g). The NRC supports the use of technological advancements to improve the quality of information included on the Federal CCF (*e.g.*, legibility, accuracy, and completeness of information); reduce undue delays and/or the canceling of specimen tests due to paperwork irregularities; facilitate timely transmission of information to and from collectors, laboratories, and responsible licensee representatives (*e.g.*, the MRO); and reduce recordkeeping and reporting costs.

Lot. This final rule adds a definition for *lot* to § 26.5, representing units that have the same starting materials, performance characteristics, and expiration date. The term is used in 10 CFR part 26 but is not currently defined. Adding this definition improves consistency between 10 CFR part 26 and the definition of *lot* in Section 1.5 of the 2008 and 2017 HHS Guidelines and enhances the clarity of 10 CFR part 26. This final rule uses the same definition in the 2008 HHS Guidelines by defining *lot* as a number of units of an item manufactured from the same starting materials within a specified period of time for which the manufacturer states that the items have essentially the same performance characteristics and the same expiration date. This final rule also includes in the definition the parenthetical statement from the 2008 HHS Guidelines definition that provides examples of the term "item." The NRC is changing one of the examples in the parenthetical statement by replacing "quality control material" with "quality control samples." The term "quality control material" is not used in 10 CFR part 26.

Rejected for testing. This final rule adds to § 26.5 a definition for *rejected for testing* that is similar to the definition in Section 1.5 of the 2008 and 2017 HHS Guidelines, referring to a report by an LTF or HHS-certified laboratory that no tests can be performed on a specimen. The term *rejected for testing* appears in § 26.169(h)(8) but currently is not defined. Including a definition clarifies what information is being reported by

the HHS-certified laboratory to the licensee or other entity in the annual quantitative summary of test results. In addition, defining the term aligns with two additional changes to §§ 26.129(b)(1)(ii) and 26.159(b)(1)(ii), clarifying the existing step that an LTF or HHS-certified laboratory would take, if a licensee or other entity had reason to question the integrity and identity of a specimen (*i.e.*, reject the specimen for testing). In § 26.129(b)(1)(ii), the phrase “the specimen may not be tested” is replaced with the phrase “the licensee testing facility shall reject the specimen for testing.” In § 26.159(b)(1)(ii), the phrase “the specimens may not be tested” is replaced with the phrase “the laboratory shall reject the specimens for testing.” Improving the consistency of terminology used when a specimen cannot be tested improves the regulatory efficiency of 10 CFR part 26.

Responsible Person. This final rule adds a definition for *Responsible Person* to § 26.5. The position title is used in § 26.31(d)(1)(D) but currently is not defined. A *Responsible Person* is defined as the person at the HHS-certified laboratory who assumes professional, organizational, educational, and administrative responsibility for the day-to-day management of the HHS-certified laboratory. Adding this definition from the HHS Guidelines improves consistency between 10 CFR part 26 and the 2008 and 2017 HHS Guidelines and the clarity of 10 CFR part 26. A conforming change is made to § 26.167(f)(3) to capitalize the position title in the phrase “a statement by the laboratory’s responsible person.”

Calibrator. This final rule revises the definition for *calibrator* in § 26.5 to align more closely with the definition in Section 1.5 of the 2008 HHS Guidelines and to improve internal consistency of terminology used in 10 CFR part 26. The definition of *calibrator* is revised to include a clarifying statement that a calibrator is a solution of known concentration “in the appropriate matrix.” This change aligns NRC’s definition with the definition in the 2008 HHS Guidelines. The phrase “test specimen/sample” in the definition of *calibrator* is replaced with the phrase “donor specimen or quality control sample” and improves consistency with the terminology used in 10 CFR part 26. The revised definition deletes the last sentence of the current definition, “calibrators may be used to establish a cutoff concentration and/or a calibration curve over a range of interest.”

Although a part of this sentence aligns with the 2008 HHS Guidelines, the sentence is not a definition, but rather

a voluntary provision that a laboratory may use a calibrator to establish a calibration curve. The determination of calibration curves is an internal laboratory process that already must be described in standard operating procedures for LTFs in § 26.127, “Procedures,” and is evaluated during NLCP inspection of HHS-certified laboratories.

Control. This final rule revises the definition of *control* in § 26.5 to conform to the definition of the term in Section 1.5 of the 2008 and 2017 HHS Guidelines and enhance the clarity of 10 CFR part 26. The term *control* in § 26.5 is revised by replacing the phrase “a sample used to monitor the status of an analysis to maintain its performance within predefined limits” with the phrase “a sample used to evaluate whether an analytical procedure or test is operating within predefined tolerance limits.”

Dilute specimen. This final rule revises the definition of *dilute specimen* in § 26.5 to conform to the definition of the term in Section 1.5 of the 2008 and 2017 HHS Guidelines. The phrase “concentrations that are lower than expected for human urine” is revised to read as “values that are lower than expected but are still within the physiologically producible ranges of human urine.” The current definition incorrectly references “concentrations,” which does not apply to a specific gravity reading. The current definition also does not clearly state that lower than expected creatinine and specific gravity measurements in a dilute specimen are still within the range that could be produced by a human being.

HHS-certified laboratory. The current definition of an *HHS-certified laboratory* in § 26.5 lists the **Federal Register** citation for each final version of the HHS Guidelines (originally published in 1988, and amended in 1994, 1998, and 2004). Under this definition, an HHS-certified laboratory must meet the 2004 HHS Guidelines, which were published on April 13, 2004 (69 FR 19643). No laboratory performing testing for 10 CFR part 26 licensees or other entities currently meets this definition because the definition refers to the superseded 2004 HHS Guidelines; rather, HHS certifies a laboratory to the HHS Guidelines that are in effect at the time that HHS certifies the laboratory. In the proposed rule, the NRC corrected this restriction by defining an *HHS-certified laboratory* as a laboratory that is certified to meet the standards of the HHS Guidelines at the time that drug and validity testing of a specimen is performed for a licensee or other entity. This change to the definition of *HHS-*

certified laboratory eliminates the need to revise 10 CFR part 26 should future versions of the HHS Guidelines be published. This final rule removes the term “drug and validity” that was included in the proposed definition because the NRC specifies in other sections of 10 CFR part 26 the types of tests that must be performed on specimens.

Additionally, this final rule adds the statement “and performs that testing for a licensee or other entity in accordance with the HHS Guidelines, unless otherwise specified in this part.” The NRC is adding this new statement to the definition to clarify that not only must an *HHS-certified laboratory* be certified to meet the HHS Guidelines, but the 10 CFR part 26 testing for the licensee or other entity must be performed as required by the HHS Guidelines unless a provision in 10 CFR part 26 states otherwise. This change is based, in part, on a response to a specific request for comment in the proposed rule. As described in Section II.B.3 of this document, the NRC is revising § 26.161(h) to allow licensees and other entities to use more stringent cutoff levels for validity testing than those specified in § 26.161 only if the testing is performed at an *HHS-certified laboratory*. The addition of the new statement in the definition of *HHS-certified laboratory* ensures that the more stringent cutoff levels will be consistent with the HHS Guidelines current as of the date of the validity testing.

This final rule includes two conforming changes made as a result of the revised definition for *HHS-certified laboratory*. First, the phrase “HHS-certified laboratories as defined in § 26.5” is added to §§ 26.4(j)(3) and 26.153(a). Second, the reference in § 26.153(a) to the physical address of SAMHSA’s Division of Workplace Programs as the location to obtain information concerning the certification status of laboratories has been removed.

Invalid result. This final rule revises the definition of *invalid result* in § 26.5 to be consistent with the definition of the term in Section 1.5 of the 2008 and 2017 HHS Guidelines and improve the clarity and accuracy of the NRC’s requirements in 10 CFR part 26. The current definition does not include the specific criteria under which a laboratory will report an invalid test result for a specimen. The phrase “for a specimen that contains an unidentified adulterant, contains an unidentified interfering substance, has an abnormal physical characteristic, contains inconsistent physiological constituents, or has an endogenous

substance at an abnormal concentration that prevents the laboratory from completing testing or obtaining a valid drug test result” is replaced with “in accordance with the criteria established in § 26.161(f) when a positive, negative, adulterated, or substituted result cannot be established for a specific drug or specimen validity test.” The revised definition also corrects an inaccuracy in the current definition of *invalid result*, which does not include “specimen validity test.”

Limit of Quantitation. This final rule revises the definition for *limit of quantitation (LOQ)* in § 26.5 to align more closely with Section 1.5 of the 2008 and 2017 HHS Guidelines and enhance the clarity of 10 CFR part 26. In the proposed rule, the NRC noted that its proposed definition would continue to use “analyte” instead of the HHS term, “measurand.”⁴ However, the 2017 HHS Guidelines replaced “measurand” with “analyte.”

Substituted specimen. This final rule revises the definition of *substituted specimen* in § 26.5 to align with the definition of the term in Section 1.5 of the 2008 and 2017 HHS Guidelines. The phrase “specimen with creatinine and specific gravity values that are so diminished or so divergent that they are not consistent with normal human physiology” is replaced with “a specimen that has been submitted in place of the donor’s urine, as evidenced by creatinine and specific gravity values that are outside the physiologically producible ranges of human urine.”⁵ The revision improves the clarity of the rule by explaining that a substituted specimen is the result of donor action to subvert the testing process: “a specimen that has been submitted in place of the donor’s urine.”

Drug Testing Panel Additions

This final rule adds two amphetamine-based chemical compounds—methylenedioxymethamphetamine (MDMA) and methylenedioxyamphetamine (MDA)—to the NRC-required drug testing panel, consistent with the drug testing panel in Section 3.4 of the 2008 and 2017 HHS Guidelines. MDMA (also known as Ecstasy or Molly) and MDA are listed on Schedule I of the Schedules of Controlled Substances (21 CFR 1308.11). A Schedule I drug or

substance has a high potential for abuse, has no currently accepted medical use in treatment in the United States, and there is a lack of accepted safety for use of the drug or substance under medical supervision (21 U.S.C. 812). This final rule adds testing for MDMA and MDA because of their potential adverse effects on human performance, which were detailed by HHS in the notice of proposed revisions to the HHS Guidelines, published in the **Federal Register** on April 13, 2004 (69 FR 19673). The proposed rule also included testing for an additional amphetamine-based chemical compound, methylenedioxyethylamphetamine (MDEA), consistent with the 2008 HHS Guidelines. However, the final rule does not include testing for MDEA as it was subsequently removed in the 2017 HHS Guidelines because HHS determined that the number of positive MDEA specimens reported from its certified laboratories did not support continued testing for the substance.

This final rule also adds four opioids (*i.e.*, hydrocodone, hydromorphone, oxycodone, and oxymorphone) to the NRC-required drug testing panel. The NRC made the change in response to comments received on the proposed rule, as discussed in Section II.B.6 of this document, and to fully align with Section 3.4 of the 2017 HHS Guidelines. Each of the opioids is listed on Schedule II of the Schedules of Controlled Substances (21 CFR 1308.12). A Schedule II drug or substance has a high potential for abuse, has a currently accepted medical use in treatment in the United States or a currently accepted medical use with severe restrictions, and abuse of the drug or substance may lead to severe psychological or physical dependence. HHS recommended the addition of these opioids in its notice of proposed revisions to the HHS Guidelines published on May 15, 2015 and based its decision on drug abuse trends and the scientific ability to test for these substances.

By requiring licensees and other entities to test for additional substances, a greater range of addictive drugs that impair human performance can be detected. Testing for additional substances may also identify individuals using illegal drugs, a characteristic of not being trustworthy and reliable.

This final rule revises §§ 26.31(d)(1) and 26.405(d) to include hydrocodone, hydromorphone, MDMA, MDA, oxycodone, and oxymorphone in the list of substances that licensees and other entities are required to test. This final rule adds these six substances to the

initial drug testing tables that appear in § 26.133, “Cutoff levels for drugs and drug metabolites,” and § 26.163(a)(1) for LTFs and HHS-certified laboratories, respectively. The six substances also are added to the confirmatory drug testing table that appears in § 26.163(b)(1) for HHS-certified laboratories. This final rule also adds two new tables to § 26.163(a)(1) and (b)(1) that specify the substances and cutoff levels for initial and confirmatory testing of oral fluid specimens, as further discussed in Section II.C of this document, under “Acceptable Specimens for Observed Collection.” The tables throughout 10 CFR part 26 are accordingly retitled and renumbered.

This final rule replaces the terms “opiate” and “opiates” with “opioid” and “opioids,” respectively. An opiate is a naturally occurring substance found in the opium poppy plant (*Papaver somniferum*). Codeine and morphine are opiates. The addition of hydrocodone, hydromorphone, oxycodone, and oxymorphone to the required drug testing panel in this final rule necessitates a terminology change because each of these substances is a semi-synthetic opioid, which means it is synthesized in a laboratory using a naturally occurring opium product. It is more accurate to refer to these substances under the more inclusive drug class term “opioid,” which includes the plant-based substances and those synthesized in laboratories. This terminology change is consistent with Section 3.1(b) of the 2017 HHS Guidelines. This final rule replaces the term “opiates” with “opioids” in §§ 26.31(d)(1), 26.163(b)(1), 26.169(h)(3)(iii), and 26.405(d). This final rule replaces the term “opiate metabolites” with “opioids” in the initial test cutoff level tables in § 26.133 and 26.163(a)(1).

The reporting requirement for HHS-certified laboratories in § 26.169(c)(2) is revised to remove the word “opiate” from the phrase “confirmatory opiate test results for morphine or codeine.” The word opiate is unnecessary in this sentence because each applicable substance is listed.

This final rule revises § 26.185(j) introductory text to replace “opiates” with “opioids” in the first sentence. Section 26.185(j)(1) is revised to replace “opiates” with “opioids (*i.e.*, codeine and/or morphine)” and to replace the statement “opium, an opiate, or an opium derivative (*e.g.*, morphine/codeine)” with “morphine and/or codeine.” The addition of hydrocodone, hydromorphone, oxycodone, oxymorphone to the drug testing panel in this final rule is the basis for these

⁴ “Analyte” means the drug or drug metabolite measured by an initial or confirmatory drug test.

⁵ “Creatinine” means a substance that is created in a human being as a result of muscle metabolism and is excreted in urine. The creatinine concentration of each urine specimen is measured by validity testing.

changes. Clarifying that the evaluation for the clinical signs of abuse is limited to positive test results for the opiates morphine and codeine is necessary because these two substances can be consumed in food. The HHS document, “Medical Review Officer Manual for Federal Workplace Drug Testing Programs,” provides information on the review of opioid tests results, both for the existing substances tested for under 10 CFR part 26 (codeine, morphine, and 6-AM) and also for the additional opioids added in the 2017 HHS Guidelines. The manual states—

The opioid drug class poses some unique challenges with regard to interpretation because a positive result may be for a legitimate source, including the following: Codeine and morphine may be present due to the consumption of poppy seeds; and] a positive result for any of the opioid analytes (with the exception of 6-AM) may be from legitimate use of a drug product.

The MRO manual also states that hydrocodone, hydromorphone, oxycodone, and oxymorphone are not found in food products and are therefore subject to review as the only appropriate use is by prescription. The 2017 HHS Guidelines in Section 13.4(d)(1) provided for the MRO review of laboratory test results and stated that if the donor is unable to provide a legitimate medical explanation, then the MRO reports a positive result to the agency for all drugs except codeine and morphine.

This final rule also replaces the term “opiates” with “opioids” in § 26.185(j)(2), which applies to the MRO review of a “positive confirmatory test result for drugs other than opiates,” and in § 26.185(j)(4), which states that the MRO may consider the use of medication from a foreign country for “a positive confirmatory test result for opiates.”

This final rule also expands the NRC-required drug testing panel to include initial testing for 6-AM, consistent with Section 3.4 of the 2008 and 2017 HHS Guidelines. This change improves the assurance that the testing method used under 10 CFR part 26 identifies individuals using heroin, a Schedule I drug. Currently, 10 CFR part 26 only permits the testing of a specimen for 6-AM when the specimen also tests positive for morphine (*i.e.*, the morphine concentration is greater than the confirmatory testing cutoff level). The HHS implemented initial testing for 6-AM in the 2008 HHS Guidelines based on the analysis of laboratory testing data that demonstrated that 6-AM was detectable in the specimens of some individuals even when the specimens tested negative for morphine.

Performing initial testing for 6-AM also improves the speed at which testing is completed for this heroin metabolite. Initial drug testing is typically completed on a specimen within 24 hours of receipt at an HHS-certified laboratory. Confirmatory testing can take several days, depending on when the laboratory performs testing on specimens for a particular drug or drug metabolite. Because the current testing for 6-AM is only performed after initial and confirmatory testing of morphine returns a positive test result, it is typical for a laboratory to take the full 5 business days permitted under § 26.169(a) to complete 6-AM testing and then report that result to the MRO for review. This final rule change to conduct initial testing for 6-AM independent of morphine will improve how quickly an HHS-certified laboratory will complete testing, which is of critical importance for any individual actively performing duties that subject them to the requirements of 10 CFR part 26.

This final rule updates the test result information that each HHS-certified laboratory must include in the annual statistical summary report provided to a licensee or other entity under § 26.169(h)(3) by adding hydrocodone, hydromorphone, MDMA, MDA, oxycodone, and oxymorphone to the reporting requirements. This final rule also revises § 26.169(h), as further discussed in Section I.C of this document under the topic “Acceptable Specimens for Observed Collection.”

Revised Initial Drug Testing Cutoff Levels

The 2008 HHS Guidelines established the scientific and technical bases for lowering the initial drug testing cutoff levels for testing urine specimens for amphetamines and cocaine metabolites. This final rule updates the cutoff levels for initial drug testing of urine, as listed in the table in § 26.133 for testing performed at LTFs, and in the table in § 26.163(a)(1) for testing performed at HHS-certified laboratories. The changes to §§ 26.133 and 26.163(a)(1) conform with Section 3.4 of the 2008 and 2017 HHS Guidelines. Specifically, this final rule makes the following changes in each table: (1) lowers the initial test cutoff level for cocaine metabolites, (2) replaces the term “opiate metabolites” with “codeine/morphine” to clarify the existing testing requirement and includes a new footnote 1 to clarify that the target analyte for “codeine/morphine” testing is morphine, (3) lowers the initial test cutoff level for amphetamines (abbreviated in the tables as AMP), (4) clarifies in a new footnote

2 that either a single or multiple initial test kit(s) may be used for amphetamines testing, and (5) includes a new footnote 3 to clarify that methamphetamine (abbreviated in the tables as MAMP) is the target analyte for amphetamines and methamphetamine testing. The column header “Drug or metabolites” in each table is revised to “Drugs or drug metabolites” to align with the table title.

Lowering the cutoff levels for these existing drugs and drug metabolites in the NRC-required testing panel increases the timeframe (*i.e.*, the window of detection) in which these drugs can be detected in an individual’s urine after use and may also lead to improved deterrence. Increasing the window of detection for these substances provides a higher degree of assurance that persons who are using illegal drugs or misusing legal drugs would be identified. The NRC anticipates that the lower testing cutoff levels will increase the number of urine specimens identified as containing amphetamine, cocaine metabolite, and methamphetamine. These anticipated outcomes are based on increases in detection reported by Federal employee workplace drug testing programs and the DOT testing program subsequent to implementing the lower testing cutoff levels in the 2008 HHS Guidelines, as discussed in the regulatory basis and the regulatory analysis for this final rule.

In addition, this final rule revises §§ 26.133 and 26.163(a)(1) to clarify that the specified testing cutoff levels are used by an LTF or an HHS-certified laboratory to determine whether a specimen is either “negative” or “positive” for each drug or drug metabolite being tested. This change better aligns 10 CFR part 26 with Section 11.19(b) and (c) of the 2008 and 2017 HHS Guidelines, which require the HHS-certified laboratory to make a determination that each specimen is either “negative” or “positive” for each drug and drug metabolite tested.

Revised Confirmatory Drug Testing Cutoff Levels

The 2008 HHS Guidelines established the scientific and technical bases to justify lowering the confirmatory drug testing cutoff levels for testing urine specimens for amphetamine, the cocaine metabolite benzoylecgonine, and methamphetamine.

The NRC is lowering the cutoff levels for confirmatory drug tests for urine, as listed in the table in § 26.163(b)(1), to align with Section 3.4 of the 2008 and 2017 HHS Guidelines. Specifically, this final rule makes the following changes: (1) lowers the confirmatory test cutoff

levels for amphetamine, cocaine metabolite, and methamphetamine, (2) eliminates table footnote 3, which specified the requirement that confirmatory testing of 6-AM only proceed when confirmatory testing shows a morphine concentration exceeding 2000 ng/mL;⁶ and (3) redesignates table footnote 4 as footnote 3 and updates the text to lower the amphetamine concentration that also must be present in a specimen for it to be determined positive for methamphetamine. Similar to the changes made to the initial testing cutoff levels, lowering the confirmatory testing cutoff levels for amphetamine, cocaine metabolite, and methamphetamine increases the timeframe in which these drugs can be detected in an individual's urine after use and may also add to the deterrent effect of the rule. In addition, this final rule makes two clarifying changes to the initial drug testing cutoff level table for urine specimens in § 26.163(b)(1) by replacing "Opiates" with "Opioids" and adding the abbreviation "(6-AM)" after 6-acetylmorphine. The change to "Opioids" is necessary because of the addition of hydrocodone, hydromorphone, oxycodone, and oxymorphone in this final rule.

Finally, the column header "Drug or metabolites" in the table in § 26.163(b)(1) is revised to "Drugs or drug metabolites" to align with the table title. These changes improve consistency with Section 3.4 of the 2008 and 2017 HHS Guidelines and with the revisions to §§ 26.133 and 26.163(a)(1).

This final rule makes conforming changes to the § 26.169(h)(3) annual statistical summary reporting requirements that apply to HHS-certified laboratories, by improving the clarity and uniformity of the names of the drugs and drug metabolites. Specifically, this final rule adds "(as THCA)"⁷ after "Marijuana metabolite," adds "(as benzoylecgonine)" after "Cocaine metabolite," revises "6-AM" to "6-acetylmorphine (6-AM)," and revises "Phencyclidine" to "Phencyclidine (PCP)."

Validity Testing of Adulterants at HHS-Certified Laboratories

This final rule revises the decision point used in the validity tests performed by HHS-certified laboratories, as described in § 26.161(c)(3) through (c)(6) and § 26.161(f)(5) and (f)(7), by replacing the

limit of detection (LOD) with the limit of quantitation (LOQ) as the decision point for determining if a specimen contains an adulterant (*i.e.*, adulterated test result) or the possible presence of an adulterant (*i.e.*, invalid test result). The difference between the LOD and the LOQ for a testing assay is the ability to reliably quantify the analyte. At the LOD, the validity test must meet all HHS-certified laboratory criteria for result acceptance, except quantitation. At the LOQ, the validity test must reliably confirm the presence of the analyte, reliably quantify the concentration of the analyte, and meet all HHS-certified laboratory criteria for result acceptance. Use of the LOQ provides an additional donor protection on the accuracy of validity testing (*i.e.*, in making the conclusion that results are adulterated or invalid).

The changes in this final rule to § 26.161(c)(3) through (c)(6) are consistent with Section 3.5 of the 2008 HHS Guidelines and Section 3.6 of the 2017 HHS Guidelines, which describe the validity testing criteria for the adulterants chromium (VI), halogen (*e.g.*, bleach, iodine, fluoride), glutaraldehyde, and pyridine (pyridinium chlorochromate). The changes in this final rule to § 26.161(f)(5) and (f)(7) are consistent with the validity testing criteria in Section 3.8 of the 2008 HHS Guidelines and Section 3.9 of the 2017 HHS Guidelines for invalid test results due to the possible presence of halogen or an oxidizing adulterant.

The NRC did not change the initial validity testing requirement in § 26.131(b)(5) that applies to LTF testing for the possible presence of halogen. Section 26.131(b)(5) currently permits an LTF to use a "halogen colorimetric test (halogen concentration equal to or greater than the limit of detection (LOD))." The NRC did not change the use of LOD in this instance, because LTFs already must send any specimen identified with the possible presence of an adulterant to an HHS-certified laboratory for initial and confirmatory validity testing, where the LOQ of the test would be utilized.

This final rule revises § 26.161(c)(5) and (c)(6) to permit HHS-certified laboratories to conduct confirmatory validity testing for the adulterants glutaraldehyde and pyridinium chlorochromate using "a different confirmatory method (*e.g.*, gas chromatography/mass spectrometry (GC/MS))" instead of what is currently required, which is only "GC/MS for the confirmatory test." This final rule provides additional flexibility in the confirmatory testing methods that may

be used by the laboratory and aligns with similar testing requirements in § 26.167(e)(1), the current version of § 26.153(c) (as described in the Statement of Considerations for the 2008 FFD final rule, see 73 FR 17091 and 17102), and Section 11.19(d) of the 2008 and 2017 HHS Guidelines.

Special Analyses Testing of Urine Specimens

Special analyses testing is an NRC testing methodology introduced in the 2008 FFD final rule to address the circumstance where a donor consumes a large quantity of fluid just before providing a urine specimen for testing in the hope of diluting the concentration of any drugs and drug metabolites in the specimen below the testing cutoff levels to avoid detection (*i.e.*, to produce a negative drug test result). This testing methodology is not included in the HHS Guidelines, but provides licensees and other entities with an added level of assurance that an individual with a dilute specimen is not attempting to hide drug use. Section 26.163(a)(2) currently provides each licensee and other entity with the option to require the HHS-certified laboratory to conduct special analyses of dilute specimens (*i.e.*, conduct confirmatory testing to the LOD for drugs and drug metabolites when the immunoassay response of the initial drug test is equal to or greater than 50 percent of the cutoff calibrator). For example, if a specimen is dilute and the initial test for marijuana metabolites measured a concentration of 25 ng/mL (the initial cutoff level for marijuana metabolites is 50 ng/mL), special analyses testing would then be performed on the specimen. Using a lower cutoff level for the testing of a dilute specimen enhances the ability of licensees and other entities to identify drug-using individuals attempting to avoid detection through the consumption of large quantities of fluid just before providing a specimen for testing.

This final rule makes four changes to the special analyses testing requirements in § 26.163(a)(2). First, this final rule requires all licensees and other entities to conduct special analyses testing of dilute specimens. An analysis of the NRC's FFD program performance reports for calendar years 2011 through 2019 demonstrates the effectiveness of special analyses testing because these data show that additional positive results were identified for pre-access, random, and post-event special analyses tests. As of 2019, 93 percent of licensees and other entities have adopted the special analyses testing policy. This final rule eliminates

⁶ The unit ng/mL is nanograms per milliliter or a millionth of a gram per liter.

⁷ THCA is an abbreviation for delta-9-tetrahydrocannabinol-9-carboxylic acid.

references to the option for licensees and other entities to conduct special analyses testing of specimens with dilute validity test results that appear in §§ 26.31(d)(1)(ii); 26.163(a)(1) and (b)(1); 26.183(c), (c)(1), and (d)(2)(ii); and 26.185(g)(2) and (3). These tests are now required.

Second, this final rule lowers the immunoassay percentage response for initial testing in § 26.163(a)(2)(ii) that HHS-certified laboratories must use to determine if special analyses testing is to be conducted. This final rule lowers the immunoassay response from “equal to or greater than 50 percent of the cutoff calibrator” to “equal to or greater than 40 percent of the cutoff calibrator.” Use of a lower cutoff level to evaluate the immunoassay response could increase the number of specimens subject to special analyses testing and improves the ability of licensees and other entities to identify drug-using individuals attempting to subvert the drug testing process. This change does not affect the drug testing assays used by HHS-certified laboratories because under the HHS Guidelines, each laboratory must already validate the accuracy of each assay to 40 percent of the cutoff calibrator. Each laboratory will need to change its administrative procedures that define the initial test result concentrations that trigger special analyses testing.

Third, this final rule replaces the LOD with the LOQ as the confirmatory drug testing cutoff level to be used by HHS-certified laboratories when conducting special analyses testing. Currently, § 26.163(a)(2)(ii) requires the use of the LOD as the cutoff level for special analyses testing of dilute specimens. The difference between the LOD and the LOQ for a drug testing assay is the ability to reliably quantify the analyte. At the LOD, the confirmatory drug test must meet all HHS-certified laboratory criteria for result acceptance except quantitation. At the LOQ, the confirmatory drug test must reliably confirm the presence of the analyte, reliably quantify the concentration of the analyte, and meet all HHS-certified laboratory criteria for result acceptance. The LOQ provides an additional donor protection on the accuracy of special analyses test results. To receive and maintain laboratory certification by the NLCP, HHS-certified laboratories must already determine both the LOD and LOQ for each drug testing assay. Therefore, changing the decision point from the LOD to the LOQ for reporting confirmatory drug test results does not result in changes to the testing assays used at the laboratories.

The NLCP also requires all HHS-certified laboratories to validate the accuracy and precision of each confirmatory drug test at or below 40 percent of the cutoff. To meet this testing specification, the laboratory must establish both the LOD and the LOQ below the 40 percent cutoff, which results in variability among laboratories on how far below the 40 percent cutoff the LOD and LOQ are established. This is dependent, in part, on the instrumentation and testing processes used at the laboratory. The NRC acknowledges this variability. Some attendees at public meetings requested a standardized level be used across all laboratories performing special analyses testing. However, this position is contrary to the 10 CFR part 26 regulatory framework that enables licensees and other entities to use lower cutoff levels in the testing for drugs and drug metabolites, as permitted under § 26.31(d)(3)(iii).

Fourth, this final rule expands the special analyses testing requirement in § 26.163(a)(2)(i) to include the testing of some specimens collected under direct observation. Section 26.115(a) describes the exclusive grounds for performing a directly observed collection. Under the current requirements, a directly observed collection may be performed when sufficient information has been obtained during the collection process or in the testing of a previous specimen to indicate a possible subversion attempt by the donor or when an individual has a confirmed positive drug test result on a prior occasion. As such, a directly observed collection after either of these circumstances provides additional assurance that the subsequent specimen obtained for testing came directly from the donor's body and was not altered to avoid detection of drug use. Likewise, special analyses testing provides additional assurance that drugs and drug metabolites present in the specimen collected under direct observation from a donor will be identified, which improves the MRO's ability to determine whether a subversion attempt was made on the initial specimen collected from the donor. For example, an initial unobserved specimen provided by a donor is determined by the collector to be out of the acceptable temperature range specified in § 26.111(a) and tests negative for drugs, and the second specimen collected under direct observation from the donor tests positive for a drug. In this example, the differences in test results from the initial and second specimen collected provide conclusive evidence to the

MRO to make a subversion determination on the initial specimen provided. Therefore, this final rule revises § 26.163(a)(2)(i) to require that special analyses testing be performed on specimens collected through directly observed collections under § 26.115(a)(1) through (3), and (a)(5).

Section 26.115(a)(1) describes the situation where a donor has presented a specimen that has been reported by an HHS-certified laboratory as adulterated, substituted, or invalid, and the MRO determines that no adequate medical explanation exists for the result and that another specimen should be collected from the donor. An analysis of the NRC's FFD program performance reports for calendar years 2011 through 2019 identified subversion attempts where the HHS-certified laboratory reported an invalid test result for the initial specimen provided by the donor and either the donor refused to provide a second specimen under direct observation or the second specimen collected under direct observation tested positive for a drug. Use of special analyses testing on the second specimen collected provides additional assurance that drug use is detected because a period of days would lapse from the point of collection of the initial specimen, testing of that specimen at a laboratory, MRO review of the test results and discussion with the donor, MRO determination that a second specimen should be collected, and the donor appearance at a collection site to provide a second specimen under direct observation.

Section 26.115(a)(2) describes the situation where a donor provides a specimen that falls out of the acceptable temperature range specified in § 26.111(a). Section 26.115(a)(3) describes the situation where donor conduct during the collection process indicates an attempt to dilute, substitute, or adulterate the specimen. An analysis of the NRC's FFD program performance reports for calendar years 2011 through 2019 demonstrates that the majority of subversion attempts are identified based on information obtained during the specimen collection process by the collector (e.g., specimen temperature) and the collection of a second specimen from the donor under direct observation. Use of special analyses testing in these two instances provides additional assurance that the drug use is detected in the second specimen collected under direct observation because the information from the initial collection process indicated a possible subversion attempt.

Section 26.115(a)(5) addresses the situation where the MRO verifies that a

specimen is positive, adulterated, or substituted; the donor requests that a retest of the specimen be performed at a second HHS-certified laboratory, but the specimen is not available for testing. As a result, the confirmed test result from the initial testing laboratory must be cancelled by the MRO because the donor was not afforded the opportunity to verify the test results through additional testing at a second HHS-certified laboratory. Use of special analyses testing in this instance provides additional assurance for the same reason described for specimens collected under § 26.115(a)(1).

The change in this final rule to require special analyses testing of specimens collected under direct observation will require licensees and other entities to establish an approach for the licensee or other entity to use when notifying a laboratory that special analyses testing is required for a specimen.

Alternative Specimen Collection Sites

Sections 26.4(e)(6)(iv) and 26.31(b)(2) include the statement that licensees and other entities may rely on a local hospital or other organization that meets the requirements of 49 CFR part 40, “Procedures for Department of Transportation Workplace Drug and Alcohol Testing Programs (65 FR 41944; August 9, 2001).” Section 26.415(c) also includes a statement that licensees and other entities need not audit the specimen collection and alcohol testing services that meet the requirements of 49 CFR part 40, “Procedures for Department of Transportation Workplace Drug and Alcohol Testing Programs (65 FR 41944; August 9, 2001).” This final rule eliminates the **Federal Register** citation from each of these 10 CFR part 26 sections because the DOT final rule found on page 41944 in the August 9, 2001, edition of the **Federal Register** no longer represents the current version of 49 CFR part 40. The intent of these provisions is to provide licensees and other entities with flexibility to utilize collection sites that meet the DOT specimen collection requirements in 49 CFR part 40. Listing the specific **Federal Register** notice of the applicable DOT final rule is not necessary because the existing requirements in §§ 26.4(e)(6)(iv), 26.31(b)(2), 26.405(e), and 26.415(c) already specify that the local hospital or other organization must meet the requirements in 49 CFR part 40.

Specimen Collection Procedures

This final rule revises a number of specimen collection procedures in 10 CFR part 26 to (1) clarify and enhance

the instructions for conducting an observed collection, (2) permit the use of mirrors to assist in performing directly observed collections, (3) allow additional personnel to observe a donor who is in the hydration process following the donor’s inability to provide a specimen of adequate volume, and (4) clarify urine specimen quantity and acceptability provisions. The revisions improve the clarity, consistency, and flexibility of the collection procedures and align the NRC’s requirements more closely with the HHS Guidelines.

This final rule revises § 26.115(e), (f), and (f)(1) through (3) to clarify the instruction for conducting a directly observed specimen collection and provide consistency with Sections 4.4(a) and 8.9 of the 2008 and 2017 HHS Guidelines.

This final rule removes the first sentence in § 26.115(f), which states, “If someone other than the collector is to observe the collection, the collector shall instruct the observer to follow the procedures in this paragraph.” This final rule adds the following sentence to the end of the existing requirements in § 26.115(e): “If the observer is not a trained collector, the collector shall, in the presence of the donor, instruct the observer on the collection procedures in paragraph (f).” This change improves the clarity of the existing requirements and ensures that the donor is informed that an individual other than the collector is to observe the specimen provision and that the observer understands the procedures that must be followed to complete the specimen collection.

In § 26.115(f)(2), this final rule adds the following statement to the end of the existing requirement: “A mirror may be used to assist in observing the provision of the specimen only if the physical configuration of the room, stall, or private area used for urination is not sufficient to meet this direct observation requirement; the use of a video camera to assist in the observation process is not permitted.” This change also incorporates stakeholder feedback at the public meeting on October 11, 2011, during which the NRC proposed to prohibit the use of mirrors and video cameras to aid an observer in conducting a directly observed specimen collection, to align with Section 8.9(b) of the 2008 HHS Guidelines. Several industry participants commented that mirrors currently are used at some collection facilities where the configuration of the stall does not provide adequate space for the collector to directly observe the provision of a specimen from the

donor’s body into the specimen container. These participants suggested that if the NRC prohibited the use of a mirror to aid in the direct observation process, physical configuration changes at some collection sites would be needed.

Based on subsequent licensee and NRC inspector feedback, the NRC has concluded that the observed collection process in § 26.115(f)(1) continues to ensure that subversion paraphernalia would be identified before the provision of a specimen during the observed collection process and that the use of reflective mirrors, but not two-way mirrors, would be acceptable. As required by § 26.115(f)(1), before conducting the directly observed collection, the donor already must adjust his or her clothing to expose the area between his or her waist and knees. This step ensures that no materials to subvert the testing process (e.g., a prosthetic device, a container of synthetic urine, an ampule of an oxidizing chemical, or other subversion paraphernalia) are concealed on the donor’s body and could be used during the specimen collection. Subsequent to this step, the observer would then watch urine flow from the donor’s body into the collection cup. To accomplish this, the collector (or same-gender observer) must be in close proximity (in the stall or room where the specimen is provided) to meet this observation requirement. The use of a reflective mirror only aids in this assurance by preventing the donor’s body or the configuration of the stall or room from obstructing the collector’s view of urine flowing from the donor’s body directly into the specimen collection container. By observing the area where the urine leaves the body, the direct observation process ensures the integrity of the specimen collection process by verifying that the specimen provided is from the donor. As a result, this final rule revises § 26.115(f)(2) to permit the use of reflective mirrors.

This final rule also revises § 26.115(f)(2) to prohibit the use of video cameras to assist in visualizing the provision of a specimen under direct observation. The NRC does not consider a video camera to be an acceptable means of providing direct observation. The use of a video camera for direct observation would be inconsistent with the intent of the rule because the collector or observer would not be in the room or stall with the donor. Further, a video feed is an incomplete source of information because it may not detail the physiological characteristics associated with a subversion attempt and also cannot guarantee the privacy of

the donor beyond the individual conducting the observation.

In § 26.115(f)(3), this final rule replaces the phrase “If the observer is not the collector, the observer may not take the collection container from the donor, but shall observe the specimen as the donor takes it to the collector,” with the phrase “If the observer is not the collector, the observer may not touch or handle the collection container but shall maintain visual contact with the specimen until the donor hands the collection container to the collector.” The changes improve the clarity of the existing requirement by more closely aligning with Sections 8.9(c) and (d)(2) of the 2008 HHS Guidelines and Sections 8.10(d)(3) and (d)(4)(ii) of the 2017 HHS Guidelines and by using terminology consistent with § 26.113(b)(3).

The NRC received two public comments on the proposed rule changes to add § 26.4(g)(6) and revise § 26.109(b)(1) to improve the efficiency of FFD programs by providing licensees and other entities with flexibility in the type of personnel who may monitor a donor during the hydration process. The hydration process is the 3-hour period of time that is initiated after a donor is unable to provide an acceptable quantity of urine during the initial specimen collection attempt (*i.e.*, a shy bladder). During the hydration process, fluid is provided to assist the donor in providing a specimen of adequate volume. Provisions in the proposed rule permitted a staff member designated as FFD program personnel in § 26.4(g) to monitor the donor during the hydration process in place of the original collector. The proposed rule also contained provisions that permitted another specimen collector who met the requirements in § 26.85(a) to monitor the donor in the hydration process. The two commenters recommended that the NRC delete the proposed requirement for hydration monitors to be FFD program personnel under § 26.4(g). The commenters explained that § 26.31, “Drug and alcohol testing,” permits an individual who is not designated as FFD program personnel to monitor more significant collection processes, while receiving training only on the activities to be performed. One of the two commenters also referenced the observation process in § 26.115, “Collecting a urine specimen under direct observation,” for the same reason. To ensure proper completion of required activities, the commenters suggested that the rule be modified to include instructions to the hydration monitor on observation responsibilities.

The NRC agrees that persons monitoring a donor during the hydration process need not be designated as FFD program personnel, because 10 CFR part 26 already permits three comparable or more significant observation activities to be performed without such a restriction:

(1) Monitoring the collection of a specimen when a donor and collector have a personal relationship (§ 26.31(b)(1)(iii));

(2) Observing a donor provide a urine specimen under direct observation when a same-gender collector is not available (§ 26.115(e) and (f)); and

(3) In the exceptional event that a designated collection site is inaccessible, an immediate requirement exists to collect a urine specimen (*e.g.*, post-event test), and a same-gender collector is not available to stand outside the area to be used for the specimen collection (§ 26.87(f)(3)).

In these three instances, the individual observing the collection process must receive training or instruction on the applicable collection procedures to be permitted to perform the observation activity.

Accordingly, the NRC modified this final rule to:

(1) Remove proposed § 26.4(g)(6), which read: “All persons monitoring a donor during the hydration process described in § 26.109(b)”;

(2) Revise proposed § 26.109(b)(1) to replace the phrase “or to a hydration monitor who meets the requirements in § 26.4(g)(6)” with “or to a hydration monitor.”

This final rule retains the proposed rule requirement in § 26.109(b)(1)(i) that the original collector provide instruction to the hydration monitor on the hydration process and acceptable donor behavior.

If a hydration monitor or another collector is used, this final rule requires in § 26.109(b)(1)(ii) that the original collector document the name of the individual on the Federal CCF. The proposed rule then required under § 26.109(b)(1)(ii) that the original specimen collector provide the hydration monitor or second collector with the Federal CCF during the observation process (*e.g.*, to document the time and volume of fluid provided to the donor, to note any unusual donor behavior, and to verify that the donor is provided with 3 hours to provide a specimen). The NRC received one public comment on the proposed § 26.109(b)(1)(ii) requirement that the original specimen collector provide the Federal CCF to that hydration monitor or other collector observing the donor during the hydration process. The

commenter stated that the Federal CCF should remain with the original collector during the hydration process.

The NRC agrees that it is unnecessary for another specimen collector or hydration monitor to be provided with the Federal CCF for the hydration process because the Federal CCF would not contain enough space to document observations made during the hydration process (*i.e.*, space on the one line on the Federal CCF for comments would be limited because it already would include the name of the hydration monitor or other collector). A licensee or other entity could, consistent with its collection procedures, establish a documentation method for the hydration monitor or other specimen collector to record information about the hydration process. Accordingly, the NRC updated this final rule by removing the phrases “and then provide the Federal CCF to the individual for the duration of the hydration process” in § 26.109(b)(1)(ii), and “except as provided in § 26.109(b)(1)(ii) for the Federal CCF” in § 26.117(g).

This final rule also makes clarifying changes to § 26.109 by moving the last sentence in § 26.109(b)(1), “The collector shall provide the donor with a separate collection container for each successive specimen,” to be the new first sentence of § 26.109(b)(2). Section 26.109(b)(1) describes the procedures for providing fluid to a donor who is in the hydration process and includes the instruction to the collector to provide a separate collection container for each successive specimen provided by the donor. The instruction to provide a separate collection container for each specimen is more appropriate in § 26.109(b)(2), which describes the provision of subsequent specimens once a donor is in the hydration process.

This final rule revises § 26.89(d) in three ways. First, § 26.89(d) is revised to clarify that a collector shall conduct only one collection procedure at any given time, except in the instance when another collector who meets the requirements in § 26.85(a) or a hydration monitor is observing the donor during the hydration process, as permitted by the change to § 26.109(b)(1) in this final rule. The NRC received a public comment on a second change in the proposed rule that more precisely described the actions taken by the collector when sealing the collection container with tamper-evident tape and completing the Federal CCF to end the collection process. The proposed rule replaced the phrase “the urine specimen container has been sealed and initialed, the chain of custody form has been executed, and the donor has departed

the collection site” with the phrase “the urine specimen container has been sealed with tamper-evident tape, the seal has been dated and initialed, and the Federal CCF has been completed.” The commenter requested that the term “tamper-evident tape” be replaced with the term “tamper-evident seal” to ensure consistent use of the term, which also appears in § 26.117(c). The NRC agrees and corrects this inconsistency. Finally, the phrase “or when a refusal to test has been determined” is added to § 26.89(d) to more accurately describe when the collection process has been completed if a refusal to test has been determined. These three changes improve the clarity of the existing collection requirements, correct an editorial error in the name of the form that is used to document the specimen collection, and include a reference to a refusal to test as another circumstance when the collection process is complete.

The proposed rule included a change to § 26.89(d) to add the phrase “or when a refusal to test has been determined under § 26.107(d).” The addition of an oral fluid specimen collection and testing option in this final rule resulted in a change to the proposed addition to § 26.89(d) because § 26.107(d) applies only to refusal to test actions associated with a urine specimen collection. By removing the words “under § 26.107(d)” from the proposed phrase, § 26.89(d) now refers to “refusal to test,” a term that applies to all drug testing specimen collections.

This final rule revises § 26.107, “Collecting a urine specimen,” in four ways to clarify how the donor is observed. First, this final rule redesignates paragraph (b) as paragraph (b)(1). Second, the phrase “, except as provided in § 26.109(b)(1),” is added in the first sentence after “The collector shall pay careful attention to the donor during the entire collection process.” This revision is necessary because this final rule permits an individual other than the original specimen collector to monitor a donor in the hydration process; as a result, the original collector may not be present with the donor during the entire collection process. Third, § 26.107(b)(1) is revised to replace the phrase “to note any conduct that clearly indicates an attempt to tamper with a specimen (e.g., substitute urine is in plain view or an attempt to bring an adulterant or urine substitute into the private area used for urination)” with the phrase “to observe any conduct that indicates an attempt to subvert the testing process (e.g., tampering with a specimen; having a substitute urine specimen in plain view; attempting to bring an adulterant, urine

substitute, temperature measurement device, and/or heating element into the room, stall, or private area used for urination).” The changes in this final rule provide additional examples of subversion attempt actions that have been reported by licensees and other entities in the annual information reports required by § 26.717, “Fitness-for-duty performance data.” More accurate examples of subversion attempts in the regulatory text provide additional clarity on donor actions that may be considered a subversion attempt.

Lastly, this final rule replaces the phrase in § 26.107(b)(1), “the collector shall document the conduct” with “the collector shall document a description of the conduct.” This change clarifies the requirement. Related to this § 26.107(b)(1) requirement, the NRC received a public comment that draft regulatory guide (DG)–5040, “Urine Specimen Collection and Test Result Review under 10 CFR part 26, ‘Fitness for Duty Programs,’” specified an excessive amount of information to be documented on the Federal CCF. The commenter expressed concern that the Federal CCF did not contain sufficient space to document information regarding a subversion attempt and indicated that most licensees have internal documentation processes to capture this information. The commenter requested that the NRC revise Section C.1.B.(3) of DG–5040 to require that “a description of the donor’s conduct should be immediately documented.”

The NRC agrees, in part, that the available space on the Federal CCF is limited (*i.e.*, a single blank line to write text on the “Remarks” line of the form). Therefore, depending on the number of observations regarding a possible subversion attempt, the Federal CCF may not contain adequate space to record all information. However, the NRC disagrees with the commenter’s suggested change to eliminate the reference to documenting information on the Federal CCF in Section C.1.B.(3) of DG–5040 because it is an existing requirement in § 26.107(b)(1). Instead, the NRC revises § 26.107(b)(1) in this final rule and Section C.1.B.(3) in Regulatory Guide (RG) 5.89, “Fitness-for-Duty Programs for Commercial Power Reactor and Category I Special Nuclear Material Licensees,” to provide the collector with the option to document information about a subversion attempt on the Federal CCF or through another documentation method that is consistent with the collection procedures of the licensee or other entity. The method used by the

licensee or other entity should ensure that all information documented by the collector or hydration monitor on donor actions regarding a possible subversion attempt be provided to FFD program management to assist in the determination of appropriate next steps (*e.g.*, terminate the collection process, collect a specimen under direct observation). This final rule revises §§ 26.107(d)(3) and 26.111(b), which also require the collector to document observations on the Federal CCF.

Section 26.107(b)(2) is added to ensure that if a hydration monitor is used to observe a donor during the § 26.109(b) hydration process, this individual would immediately inform the collector of any donor conduct that may indicate an attempt to subvert the testing process, such as the donor leaving the collection site or refusing to follow directions. This final rule change is necessary because the collector must be informed of any unacceptable donor behavior so that appropriate action may be taken.

This final rule revises § 26.89(c) to correct an editorial error in the instructions that a collector must provide to the donor regarding refusing to cooperate with the testing process. Currently, the word “adulterated” is used twice in the phrase “adulterated, diluted, or adulterated the specimen,” which describes the situation where a donor admits to subverting the testing process. The phrase is revised to “adulterated, diluted, or substituted the specimen.”

This final rule revises § 26.117, “Preparing urine specimens for storage and shipping,” in several ways. First, this final rule revises the title of § 26.117, “Preparing urine specimens for storage and shipping,” to “Preparing drug testing specimens for storage and shipping,” replacing the word “urine” with the phrase “drug testing.” Second, this final rule revises § 26.117(a) to add the phrase “Once the collector is presented with the specimen from the donor” at the beginning of the first sentence to clarify when the collector would begin to keep the donor’s “specimen(s) in view at all times,” and remove the word “urine.” This revision improves the clarity of an existing activity in the collection process. For example, the collector would not be able to keep the donor’s urine specimen in view at all times when the donor is in the room, stall, or private area used for urination in an unobserved collection, as described in § 26.107(a). Third, this final rule corrects two editorial errors in § 26.117(f): the term “chain-of-custody forms” is replaced with the term “Federal CCFs” and the phrase “or the

licensee's testing facility" is replaced with the phrase "or to the licensee testing facility." Fourth, this final rule revises §§ 26.117(i) and (j) as further discussed in Section II.C of this document, under "Acceptable Specimens for Observed Collection."

With regard to urine specimen acceptability, this final rule revises the term "altered," as used in § 26.111(a) and (c), to clarify that the term means that the collector has determined that a specimen may have been adulterated and/or diluted. This determination by a collector is not equivalent to the determination that a specimen is an *adulterated specimen* as defined in § 26.5, which is a specimen testing determination made by an HHS-certified laboratory.

This final rule corrects an editorial error in § 26.111(a) associated with the minimum volume requirement for a urine specimen. Specifically, the phrase "but greater than 15 mL" is replaced with "but equal to or greater than 15 mL." This change conforms with the existing minimum specimen volume requirements in §§ 26.109(b)(4) and 26.111(b) and (d).

Collector Actions Following a Refusal to Test

This final rule adds § 26.107(d) and revises §§ 26.111(c) and (e) and 26.115(g) to more explicitly describe the actions that a collector must take when a refusal to test is determined during the specimen collection process, including the retention or disposal of any specimen(s) provided by the donor.

Section 26.107(d) is added by this final rule to state that if the collector determines a refusal to test during the specimen collection process, the collector shall do the following: (1) inform the donor that a refusal to test has been determined; (2) terminate the collection process; (3) document a description of the refusal to test on the Federal CCF or through another documentation method consistent with the collection procedures of the licensee or other entity; (4) discard any urine specimen(s) provided by the donor, unless the specimen was collected for a post-event test under § 26.31(c)(3); and (5) immediately inform the FFD program manager of the refusal to test. The majority of these changes are consistent with existing collector practice. However, the change to discard any urine specimens, except if collected for a post-event test, is a new requirement that improves the uniformity of licensee and other entity actions taken once a refusal to test had been determined. The NRC is aware of instances in which a licensee or other

entity would conduct specimen testing, even though a refusal to test had already been determined at the collection site. This change addresses this inconsistency. The revisions to § 26.107(d) ensure that if a donor refuses to cooperate with the collection process, uniform action is taken, which makes 10 CFR part 26 more consistent with Section 8.12 of the 2008 HHS Guidelines and Section 8.13 of the 2017 HHS Guidelines.

The final rule change to retain and test any specimen collected for a post-event test under § 26.31(c)(3) helps to inform licensee root cause determinations, as required by other parts of the NRC's regulations, such as §§ 20.2203(b), 50.73(b), and 70.50(c). Although a refusal to test determination at the collection site subsequent to a specimen being provided for a post-event test is a very rare occurrence, a regulatory framework is needed to enable the testing of an individual's urine (or other specimen matrix such as oral fluid) to assist in determining whether the individual who committed or contributed to the event may have been impaired from the use of alcohol, an illegal drug, or prescription or over-the-counter medication. This assessment (which is informed by the requirements in §§ 26.185, "Determining a fitness-for-duty policy violation," and 26.189, "Determination of fitness") is very important because post-event testing is conducted, in part, in response to the occurrence of a very significant event such as, but not limited to: (1) a death, (2) a significant illness or personal injury, (3) a radiation exposure or release of radioactivity in excess of regulatory limits, or (4) an actual or potential substantial degradation of the level of safety of the plant.

Section 26.111(c) is revised to remove the word "designated" from the phrase "designated FFD program manager." This change conforms with the existing terminology used in §§ 26.105(b), 26.109(b)(3), 26.111(c), 26.115(a), (b), and (h), and 26.139(b). The parenthetical phrase "(e.g., adulterated or diluted)" is added after the word "altered" in the second sentence of § 26.111(c) to provide additional clarity. Section 26.111(e) specifies that "as much of the suspect specimen as possible must be preserved." This final rule adds the clarifying phrase "except under the conditions described in § 26.107(d)(4)" to reference the conditions when a collector is to discard any urine specimen(s) collected. This change aligns with the changes to § 26.107(d) in this final rule.

Some participants at the public meeting on October 11, 2011, requested that the NRC consider eliminating § 26.111(f) because they believe this particular requirement is unnecessary. Section 26.111(f) defines the criteria for an acceptable urine specimen as free from apparent contaminants, of at least 30 mL in quantity, and within the acceptable temperature range. However, this requirement does not aid in the implementation of 10 CFR part 26 and is not used in the NRC's drug testing requirements. The participants stated that this provision is unnecessary because other sections in 10 CFR part 26 require specimens that do not meet the criteria in § 26.111(f) to be sent to an HHS-certified laboratory for testing. The NRC agrees that this requirement is unnecessary because other sections in the rule already provide explicit detail as to the determination of whether a specimen is valid or invalid, as well as the specific steps required if either determination is made. Section 26.109, "Urine specimen quantity," contains provisions regarding urine specimen quantity; § 26.111(a) contains provisions regarding specimen temperature; and § 26.111(d) requires that any specimen a collector suspects has been adulterated, diluted, or substituted, or that is collected under direct observation must be sent to an HHS-certified laboratory for initial and, if necessary, confirmatory testing. Therefore, this final rule removes § 26.111(f) to improve the clarity of 10 CFR part 26.

Section 26.115(g) states that a donor's refusal to allow a directly observed collection is an act to subvert the testing process. This final rule includes a new requirement that in this instance "the collector shall follow the procedures in § 26.107(d)." This new requirement describes the actions that the collector must take when a refusal to test has been determined during the specimen collection process.

Blind Performance Test Sample Lot In-Service Requirement

This final rule revises § 26.168(h)(1), which currently requires blind performance test sample (BPTS) suppliers to place a sample lot in service for no more than 6 months. Feedback received from industry and BPTS suppliers indicated that sample lots can remain viable for much longer than 6 months (e.g., 2 years). Further, Section 10.2 of the 2008 and 2017 HHS Guidelines do not impose a time limit on the use of a BPTS lot. This final rule eliminates the 6-month use limit, which enables the BPTS supplier, based on laboratory testing data on lot stability, to establish a specified shelf life for each

BPTS lot. Allowing the BPTS supplier to determine the expiration date, instead of the NRC requiring a uniform shelf life, improves the effectiveness of 10 CFR part 26, reduces costs for BPTS suppliers and entities implementing 10 CFR part 26 requirements, and aligns with the HHS Guidelines. Furthermore, if a BPTS is no longer stable and unexpected test results are reported by an HHS-certified laboratory, § 26.719(c) already requires the licensee or other entity to report to the NRC the testing error and the results of the investigation. The § 26.719(c) reporting requirement ensures that the NRC receives timely information on any BPTS formulation irregularities.

HHS-Certified Laboratory Personnel Qualifications and Responsibilities

This final rule removes § 26.155, “Laboratory personnel,” which re-states the qualifications and responsibilities of HHS-certified laboratory personnel (*e.g.*, Responsible Person, Certifying Scientist) included in the HHS Guidelines. The NRC finds that it is unnecessary to restate these HHS Guidelines requirements in 10 CFR part 26 because licensees and other entities are required to use HHS-certified laboratories as described in §§ 26.31(d)(3) and 26.153(a). Each laboratory is certified and then inspected every 6 months by the NLCP, which provides assurance that laboratory personnel are appropriately trained, qualified, and meet acceptable academic and technical requirements. This final rule change reduces the potential for dual regulation of HHS-certified laboratories because each laboratory is annually inspected by the licensee or other entity as required in § 26.41(c).

A conforming change based on the removal of § 26.155 eliminates the reference to § 26.155 in § 26.8, “Information collection requirements; OMB approval,” which lists the information collection requirements in 10 CFR part 26 that were approved by the Office of Management and Budget (OMB). A second conforming change eliminates the records retention requirement for personnel files at HHS-certified laboratories under § 26.715(b)(1).

HHS-Certified Laboratory Procedures

This final rule removes § 26.157(b) through (e), which re-state the laboratory procedures requirements included in the HHS Guidelines. Section 26.157, “Procedures,” describes the written procedures that HHS-certified laboratories must develop, implement, and maintain. The NRC finds that it is unnecessary to restate

these HHS Guidelines requirements in 10 CFR part 26 because licensees and other entities are required to use HHS-certified laboratories to conduct drug and validity testing in § 26.153(a). As previously discussed with regard to the § 26.155 changes in this final rule, each HHS-certified laboratory is certified and inspected on a periodic basis by the NLCP. This provides assurance that each laboratory meets the requirements in the HHS Guidelines to develop, implement, and maintain procedures. This final rule change reduces the potential for dual regulation of HHS-certified laboratories with respect to maintaining a duplicative set of laboratory procedures already required to be maintained by the HHS Guidelines and reviewed and evaluated by the NLCP.

This final rule revises § 26.157(a) by replacing the phrase “develop, implement, and maintain clear and well-documented procedures for accession, receipt, shipment, and testing of urine specimens” with “develop, implement, and maintain procedures specific to this part that document the accession, receipt, shipment, and testing of specimens.” The changes do the following: (1) ensure that each laboratory continues to maintain procedures specific to 10 CFR part 26, such as for special analyses testing in § 26.163(a) and the use of more stringent testing cutoff levels and/or the testing of additional substances permitted in § 26.31(d)(3); (2) remove the word “urine” from the phrase “testing of urine specimens” to provide additional flexibility, should the testing of additional specimen matrices (*e.g.*, hair) be allowed by future changes to the HHS Guidelines and subsequent amendments to 10 CFR part 26 requirements; and (3) replace “clear and well-documented” with “documented” laboratory procedures to better align with the terminology in § 26.27(c) and the 2008 and 2017 HHS Guidelines. The changes to § 26.157(a) in this final rule enhance regulatory efficiency by clarifying that each laboratory must maintain procedures specific only to 10 CFR part 26 testing.

Quality Control Samples for Validity and Drug Testing

Section 26.137(e)(6) lists the specifications for the quality control samples to be included in each analytical run of initial drug testing performed at an LTF, and § 26.167(d)(3) and (e) list the quality control sample specifications to be included in each analytical run of initial and confirmatory drug tests performed at an HHS-certified laboratory, respectively.

This final rule makes a number of conforming changes to these quality control sample requirements to improve the clarity of 10 CFR part 26 and its consistency with Sections 11.12 and 11.15(a)(1) of the 2008 and 2017 HHS Guidelines.

This final rule replaces the word “drugs” in the first sentence of § 26.137(e)(6) and the phrase “drug and metabolite” in the second sentence of § 26.137(e)(6) with “drugs and drug metabolites” and “drug and drug metabolite,” respectively. The phrases “drug(s) or drug metabolite(s)” in § 26.137(e)(6)(ii) and (e)(6)(iii) and “a drug(s) or drug metabolite(s)” in § 26.167(d)(3)(ii), (d)(3)(iii), and (e)(3)(iii) are replaced with the phrase “the drug or drug metabolite.” Similarly, the phrase “no drug” is expanded to “no drug or drug metabolite” in § 26.167(e)(3)(i), and the phrase “no drugs or drug metabolites” is revised to “no drug or drug metabolite” in §§ 26.137(e)(6)(i) and 26.167(d)(3)(i).

This final rule removes the parenthetical phrase “(*i.e.*, negative urine samples)” from §§ 26.137(e)(6)(i) and 26.167(d)(3)(i) and (e)(3)(i). Each of those requirements already specifies that the quality control sample is to contain no drug or drug metabolite, so the parenthetical is redundant.

The phrase “targeted at 25 percent below the cutoff” is replaced in this final rule with the phrase “targeted at 75 percent of the cutoff” in §§ 26.137(e)(6)(iii) and 26.167(d)(3)(iii).

The term “sample(s)” is replaced in this final rule with the phrase “at least one control” in §§ 26.137(e)(6)(i) and 26.167(d)(3)(i) and (e)(3)(i). Similarly, the phrase “at least one calibrator or control that is” is replaced in this final rule with the phrase “at least one control” in § 26.167(e)(3)(iv).

The parenthetical statement “(*i.e.*, calibrators and controls)” is added after the phrase “quality control samples” in §§ 26.137(e)(6) and 26.167(d)(4), and a conforming change is made in § 26.167(e)(2) to the phrase “calibrators and controls” by replacing it with the phrase “quality control samples (*i.e.*, calibrators and controls).”

The phrase “Positive calibrator(s) and control(s) with a drug(s) or drug metabolite(s)” in § 26.167(e)(3)(ii) is replaced in this final rule with the phrase “A calibrator with its drug concentration at the cutoff.”

This final rule replaces the phrase “A minimum of 10 percent of all specimens in each analytical run” in § 26.137(e)(6) with the phrase “A minimum of 10 percent of the total specimens in each analytical run,” to more clearly describe

how to determine the number of quality control samples to include in each analytical run of initial drug testing performed at an LTF. Conforming changes in § 26.167(e)(2) to the quality control samples that are to be included in each analytical run of confirmatory drug tests performed at an HHS-certified laboratory replace the phrase “At least 10 percent of the samples in each analytical run of specimens” with the phrase “A minimum of 10 percent of the total specimens in each analytical run.” This final rule change to § 26.167(e)(2) is consistent with the existing terminology used in the quality control sample requirement for initial drug testing in § 26.167(d)(4).

Section 26.167(f)(3) is revised to make an editorial correction to the phrase “a statement by the laboratory’s responsible person” by capitalizing the “r” and the “p” in the position title, so that it reads as follows: “Responsible Person.”

This final rule also addresses two issues that pertain to the LTF quality control sample requirements for initial validity testing in § 26.137(d)(5) and for initial drug testing in § 26.137(e)(6)(v), which were described in an NRC enforcement guidance memorandum (EGM 09–003), dated March 31, 2009. A third issue identified in EGM 09–03 on the LTF quality control sample requirements, incorrectly using the term “laboratory analysts” instead of “licensee testing facility technicians,” was addressed in a 10 CFR part 26 final rule correcting amendment (74 FR 38326; August 3, 2009).

The first issue pertains to § 26.137(d)(5) and (e)(6)(v), which require that at least one quality control sample in each analytical run must appear as a “donor specimen” to the LTF technician. To meet this requirement, a different individual would be required to prepare the quality control sample to ensure that the LTF technician that is conducting the specimen testing would be unaware of the origin of the sample. The current 10 CFR part 26 regulations do not require that the preparation of quality control samples and the conduct of specimen testing are to be performed by different individuals. Without EGM–09–003, § 26.137(d)(5) and (e)(6)(v) would have placed an unnecessary burden on licensees and other entities because additional LTF procedural changes would be necessary, including the use of an additional qualified person, either to prepare quality control samples or to conduct specimen testing. The majority of LTFs use a single LTF technician to prepare quality control samples and to perform specimen testing, which is

consistent with the intent of the current requirements. Because the LTF technician may prepare quality control samples and perform specimen testing, the technician will know when he or she is testing a quality control sample. Therefore, the appearance of the quality control sample is irrelevant. For this reason, this final rule removes the phrase “that appears to be a donor specimen to the licensee testing facility technicians” in § 26.137(d)(5) and (e)(6)(v).

The second issue pertains to the requirement in § 26.137(e)(6)(v) that “at least one positive control” is to be included in each analytical run of initial drug testing of specimens at an LTF. This requirement is already met through the requirements in § 26.137(e)(6)(ii) and (e)(6)(iii), which specify the positive quality control samples to be included in each analytical run. Furthermore, as explained in EGM 09–003, the sample required by § 26.137(e)(6)(v) does not need to be positive. This requirement is already met by § 26.137(e)(6)(i), which requires each analytical run to include sample(s) certified by an HHS-certified laboratory to contain no drugs or drug metabolites. Because the “at least one positive control” requirement in § 26.137(e)(6)(v) is unnecessary and the NRC is removing the phrase “that appears to be a donor specimen to the licensee testing facility technicians” from § 26.137(e)(6)(v), the NRC is deleting § 26.137(e)(6)(v).

The NRC is withdrawing EGM 09–003 upon the effective date of this final rule, which corrects these issues.

Additional MRO Review for Invalid Specimens With pH of 9.0 to 9.5

Section 26.185(f) describes the process that an MRO is to use to review invalid urine specimen test results. This final rule redesignates paragraph (f)(3) as paragraph (f)(4) and adds a new paragraph (f)(3) to § 26.185, to align the MRO review process for invalid specimen test results with Section 13.4(f) of the 2008 and Section 13.5(e) of the 2017 HHS Guidelines. Specifically, if a donor does not provide an acceptable medical explanation to the MRO for a pH value in the range of 9.0 to 9.5, then the MRO must consider if elapsed time and/or high temperature might have caused the test result. This change addresses research that demonstrated that exposing a urine specimen to high temperature and/or an extended delay in specimen testing from the time of collection may result in a pH in the range of 9.0 to 9.5 (Cook, et al., 2007). In this final rule, if the MRO obtains sufficient information from the licensee or other entity, collection site,

LTF, or HHS-certified laboratory regarding elapsed time and/or temperature conditions at specimen collection, receipt, transportation, or storage to conclude that an acceptable technical explanation exists for the invalid test result due to pH, then the MRO directs the licensee or other entity to collect a second urine specimen from the donor, as soon as reasonably practicable. The second specimen is not collected under direct observation because sufficient evidence was obtained to conclude that donor action likely was not the cause of the invalid test result. This new step to consider technical explanations for a discrepant pH result provides an additional protection to the donor and limits the instances in which a second collection under direct observation is necessary (*i.e.*, only for invalid specimen test results where no legitimate medical or technical explanation has been determined by the MRO). Although Section 13.4(f) of the 2008 HHS Guidelines and Section 13.5(e) of the 2017 HHS Guidelines differ in that a second test in these circumstances is not required, not requiring a second test in these circumstances is inapplicable to 10 CFR part 26 because a valid test is necessary for determining whether to grant or deny FFD authorization.

The NRC included guidance on the methods an MRO could use to review invalid test results reported under § 26.185(f)(3) in new RG 5.89, issued concurrently with this final rule.

Donor Request for Specimen Retesting or Bottle B Testing

Section 26.165(b)(2) instructs the MRO to “inform the donor that he or she may, within 3 business days of notification by the MRO of the confirmed positive, adulterated, or substituted test result, request the retesting of an aliquot of the single specimen or the testing of the Bottle B split specimen.”⁸ This final rule includes a new requirement in § 26.165(b)(2) for the MRO to document in his or her records the date and time a request was received from the donor to retest an aliquot of the single specimen or to test the Bottle B split specimen. Documenting when a donor initiated the request for testing ensures that a record is maintained to demonstrate that the donor had made

⁸ “Aliquot” means a portion of a specimen that is used for testing. It is taken as a sample representing the whole specimen. “Bottle B testing” means the drug or validity testing performed by a second HHS-certified laboratory on the split (Bottle B) specimen to verify the test results reported by the first HHS-certified laboratory that tested the Bottle A specimen.

the request within the required 3 business days. This final rule change is consistent with the existing practice of MROs documenting this information when receiving such a request.

Section 26.165(b)(3) requires the donor to provide his or her permission for the retesting of an aliquot of the single specimen or the testing of Bottle B and states that “Neither the licensee, MRO, NRC, nor any other entity may order retesting of the single specimen or testing of the single specimen or testing of the specimen in Bottle B without the donor’s written permission, except as permitted in § 26.185(l).” This final rule revises § 26.165(b)(3) to state that “No entity, other than the MRO as permitted in § 26.185(l), may order the retesting of an aliquot of the single specimen or the testing of the Bottle B split specimen.” This final rule addresses an inconsistency in the current requirements because § 26.165(b)(2) already states that the “donor’s request may be oral or in writing.” At present, even though the MRO may have received an oral request from the donor to proceed with the retesting of an aliquot of the single specimen or to test the Bottle B split specimen, some licensees are interpreting the current provision to require that the MRO must receive written permission from the donor before initiating the retesting of a specimen.

These final rule changes to § 26.165(b)(2) and (b)(3) improve the consistency of 10 CFR part 26 with Section 14.1(b) of the 2008 and 2017 HHS Guidelines and enhance due process by ensuring that the retesting of an aliquot of the single specimen or the testing of the Bottle B split specimen can proceed as quickly as possible.

Collection of a Second Specimen Under Direct Observation When Bottle B or an Aliquot of the Single Specimen Is Not Available for Testing

Section 26.115(a) lists the exclusive grounds for collecting a urine specimen under direct observation. However, the list does not include an existing requirement in § 26.165(f)(2) in which an observed collection is required when a donor requests a retest and either Bottle B or the single specimen is not available, due to circumstances outside of the donor’s control. This final rule corrects this omission by including a new paragraph (a)(5) to reference the direct observation requirement in § 26.165(f)(2).

Section 26.165(f)(2) requires MRO action for a positive drug test result or an adulterated or substituted validity test result when the Bottle B of a split specimen or an aliquot of the single

specimen is not available for testing at the donor’s request. In this instance, the MRO is required to cancel the initial test result and inform the licensee or other entity that a second specimen must be collected under direct observation “as soon as reasonably practical.” Section 14.1(c) of the 2008 and 2017 HHS Guidelines, for this same circumstance, states that no notice is to be given to the donor regarding the second specimen collection until immediately before the collection is to commence. This final rule revises § 26.165(f)(2) to specify that no prior notice shall be given to a donor until immediately before the collection. Clarifying the procedure to follow in this circumstance improves the effectiveness of licensees’ or other entities’ testing programs to detect illegal drug use and/or the misuse of legal drugs and would align 10 CFR part 26 with the 2008 and 2017 HHS Guidelines.

This final rule also revises § 26.165(f)(2) to state that the MRO is to report a cancelled test result to the licensee or other entity. The process in § 26.165(f)(2) already states that the licensee or other entity may not impose any sanctions on the donor for a cancelled test result. This revision clarifies the existing action that the MRO must take to report the results of the testing of a donor’s specimen to the licensee or other entity. Subsequent action by the licensee or other entity cannot be taken until the MRO provides the test result information for a donor’s specimen. The revision also states that the licensee or other entity must continue the administrative withdrawal of an individual’s FFD authorization until the test results from the second specimen collection are determined. Continuing to administratively withdraw an individual’s FFD authorization is consistent with § 26.165(f)(1), which requires the licensee or other entity to administratively withdraw an individual’s FFD authorization on the basis of the first confirmed positive, adulterated, or substituted test result until the results of a donor-requested Bottle B split specimen test or single specimen retest are available and have been reviewed by the MRO.

A participant at the October 11, 2011, public meeting also requested that the NRC include in § 26.165(f)(2) a reference to §§ 26.129(b)(2) and 26.159(b)(2) to clarify that the action of the licensee or other entity was taken based on the test results of the second specimen collected under direct observation. The NRC agrees with this request, and has revised this section accordingly.

FFD Program Performance Data Reporting

The NRC has periodically received questions from licensees and other entities on the annual drug and alcohol testing reporting requirements on “populations tested” in § 26.717(b)(3) and (4). Specifically, the reporting requirements to provide FFD program performance data by populations tested (*i.e.*, individuals in applicant status, permanent licensee employees, contractor/vendors (C/Vs)) has resulted in two types of questions.

First, licensees already report the pre-access testing results separately for the licensee employee and C/V tested populations, so they requested clarification on the term “individuals in applicant status.” Applicant status is not a distinct tested population category; rather, it is the status of individuals that are subject to pre-access testing. Currently, licensees and other entities must report the test results by tested population for each condition of testing (*i.e.*, pre-access, random, for-cause, post-event, and follow-up) as required by § 26.717(b)(5). By reporting the pre-access test results for each of the two tested populations (*i.e.*, licensee employees, C/Vs), licensees and other entities are already reporting the results for individuals in “applicant status.” This final rule removes the phrase “individuals in applicant status” from § 26.717(b)(3) and (4) to clarify the existing reporting requirement.

Second, the NRC has received questions from entities other than the licensees that report § 26.717 drug and alcohol test results. Because § 26.717(b)(3) and (4) do not specify “other entity” in the parenthetical statements defining the tested populations, these entities were unclear on how to classify their tested populations on the § 26.717 annual summary reports to the NRC. To correct this oversight, this final rule revises the tested population “licensee employees” to “licensee or other entity employees” in § 26.717(b)(3) and (b)(4).

Acceptable Specimens for Observed Collection

As described in Section II.B.5 of this document, this final rule is allowing a licensee or other entity to collect an oral fluid specimen instead of a urine specimen for any of the observed collection conditions in § 26.115(a)(1) through (3), and (a)(5). To provide the flexibility to conduct oral fluid specimen, the NRC has made conforming and clarifying changes in this final rule, as well as included additional new requirements specific to

the testing of oral fluid specimens. These changes, grouped by topic area, include the following:

- *Specimens to be collected.* This final rule revises the § 26.83(b) restriction to “Collect only urine specimens for both initial and confirmatory tests for drugs” by allowing the collection and testing of an oral fluid specimen for any of the observed specimen collection conditions under § 26.115(a)(1) through (3) and (a)(5), as long as the “licensee establishes through its policy and procedures that an oral fluid specimen” can be collected and tested. This final rule also requires, for each of the directly observed collection conditions in § 26.115(a)(1) through (3) and (a)(5), that a licensee or other entity always collect either urine or an oral fluid specimen.

- *Collector qualifications and responsibilities.* This final rule consolidates the urine collector requirements in § 26.85(a) and the alcohol collector requirements in § 26.85(b) into § 26.85(a), to provide uniform qualifications and responsibilities for collectors based on the specimen the collector is qualified to collect under this part. The existing urine and alcohol collector requirements are the same, with two exceptions. First, different terminology is used for “methods to address problem collections” with respect to a donor’s inability to provide a specimen: “shy bladder” for urine and “shy lung” for alcohol. This final rule addresses the terminology differences for a donor’s inability to provide a specimen by providing both terms in a parenthetical statement after “inability to provide a specimen” under § 26.85(a)(2)(i). Second, the alcohol collector qualification requirements in current § 26.85(b)(2) include the “operation of the particular testing device(s),” which is not applicable to urine collectors. This final rule revises the “operation of the particular alcohol testing devices [i.e., the alcohol screening devices (ASDs) or EBTs]” in § 26.85(b)(2) to “operation of the particular specimen collection or alcohol testing device(s) (e.g., alcohol screening device (ASD), EBT, oral fluid)” in § 26.85(a)(3). Lastly, this final rule renumbers § 26.85(a)(5), replaces the phrase “specimen collection and transfer process” with “specimen collection process,” and adds the phrase “, and the specimen transfer process, if applicable” to the end of the existing requirement. This is a conforming change necessary because “transfer process” does not apply to all specimens collected (e.g., the collection of a breath specimen for alcohol).

- *Collection sites.* This final rule revises three collection site requirements in § 26.87, “Collection sites,” to provide flexibility to collect oral fluid specimens in addition to urine specimens for drug testing. The revisions also clarify, if appropriate, that a requirement is specific to the collection of one specimen type (e.g., urine). First, § 26.87(a) is revised to replace the phrase “shipping or transportation of urine specimens to a drug testing laboratory; the collection of oral fluids or breath specimens; and the security of alcohol testing devices” with “shipping or transportation of specimens to a drug testing laboratory; the testing of specimens for alcohol; the security of specimen collection and testing devices.” Second, § 26.87(b) is revised to state that the collection site must provide visual privacy for the donor and collector during an oral fluid specimen collection. This privacy provision is consistent with the provision of individual privacy while the donor submits a urine specimen as described in § 26.87(b). Third, § 26.87(f) is revised in §§ 26.87(f) and (f)(5), to replace the term “urine specimen” with “specimen for drug testing” for an “exceptional event” that a designated collection site is inaccessible. Section 26.87(f)(2) is revised to replace the phrase “If practical, a water coloring agent” with “If practical when a urine specimen is to be collected, a water coloring agent.” Section 26.87(f)(3) is revised to replace the phrase “area that will be used for a specimen collection” with “area that will be used for a urine specimen collection.” Section 26.87(f)(4) is revised in two ways. First, the phrase “the collector shall inspect the toilet bowl and area to ensure that there is no evidence of a subversion attempt” is replaced with “if the specimen is urine, the collector shall inspect the toilet bowl and area to ensure that there is no evidence of a subversion attempt.” This change clarifies the inspection of the toilet bowl and area only applies to urine specimen collections. Second, § 26.87(f)(4) is revised to replace the phrase “the collector shall instruct the donor to participate with the collector” with “for any specimen collected for drug testing, the collector shall instruct the donor to participate with the collector.” This change clarifies that donor participation with the collector in completing the chain of custody procedures applies to any specimen collected for drug testing.

- *Preparing to collect specimens for drug testing.* This final rule revises § 26.89(d) by removing the word “urine” from the phrases “urine

collection procedure” and “urine specimen container.” These changes provide flexibility to permit the collection of any specimen for drug testing (e.g., urine, oral fluid). This final rule also revises § 26.105, “Prepare for urine collection,” to accommodate for the collection of urine and oral fluid specimens. The title of § 26.105, “Preparing for urine collection,” is revised to “Preparing for the collection of a specimen for drug testing.” In §§ 26.105(a) and (d), the word “urine” is removed from the phrase “urine specimen” where it appears. In § 26.105(c), the phrase “wash and dry his or her hands before urinating” is revised to “wash and dry his or her hands before providing a specimen.” In the first sentence of § 26.105(e), the phrase “sealed collection container from the collection kit materials” is replaced with “sealed urine specimen collection container from the collection kit materials or an oral fluid specimen collection device.” In the second sentence of § 26.105(e), the phrase “the collection container” is replaced with “urine specimen collection container.” The changes in § 26.105(e) ensure that the collection process is consistent for oral fluid and urine specimens.

- *Collecting oral fluid specimens.* This final rule revises § 26.97, “Conducting an initial test for alcohol using a specimen of oral fluids,” which was specific to the collection of oral fluid specimens for alcohol testing, by making minor conforming changes to accommodate for the collection of oral fluid specimens for both alcohol and drug testing. The title of § 26.97 is revised to “Collecting oral fluid specimens for alcohol and drug testing.” The word “test” is replaced with the phrase “specimen collection” in § 26.97(a), (a)(4), and (b)(1) through (3). Section 26.97(c)(2) is revised to replace the phrase “initial test using an EBT” with “specimen collection (i.e., initial test using an EBT for alcohol, or urine specimen collection for drug testing).” Section 26.97(d) is revised to replace the phrase “The collector shall read the result” with “For alcohol testing of oral fluids, the collector shall read the result.”

- *Preparing specimens for storage and shipping.* This final rule revises § 26.117 to accommodate for the collection of oral fluid specimens. The title of § 26.117, “Preparing urine specimens for storage and shipping,” is revised to “Preparing drug testing specimens for storage and shipping.” The first sentence in § 26.117(a) is revised to replace the phrase “Both the donor and the collector shall keep the donor’s urine specimen(s) in view” with

“Once the collector is presented with the specimen from the donor, both the donor and collector shall keep the donor’s specimen(s) in view.” In § 26.117(i), the phrase “packaged with its associated urine specimen bottle” is replaced with “packaged with its associated specimen bottle.” In the third sentence of § 26.117(j), the phrase “Specimens that have not been shipped” is replaced with “Urine specimens that have not been shipped” and the phrase “any specimen” is replaced with “any urine specimen.” A new fourth sentence is added to state that “Oral fluid specimens shall be stored under the conditions specified by the oral fluid specimen collection device manufacturer.” This new provision is necessary because the refrigeration provision for urine specimens in § 26.117(j) may not be appropriate or necessary given the buffering solution that oral fluid specimen collection devices may contain.

- *FFD program testing requirements.* Section 26.31(d)(3)(i) is revised by adding “urine” to the start of the existing requirement, “Specimens sent to the HHS-certified laboratories must be subject to initial validity and initial drug testing by the laboratory.” A new sentence is added in § 26.31(d)(3)(i) that states that “Oral fluid specimens sent to the HHS-certified laboratories must be subject to initial drug testing by the laboratory.” Unlike the collection of urine specimens that are typically provided by the donor in the privacy of a room, stall or enclosure, oral fluid specimens are directly observed by the collector. Standard validity testing is necessary for urine specimens because of the lack of direct observation of all specimens and to provide assurance that a donor has not attempted to subvert the testing process. The 2019 HHS Guidelines for oral fluid testing also do not mandate validity testing of all specimens.

- *HHS-certified laboratory specimen testing.*

- *Use of HHS-certified laboratories.* This final rule revises § 26.151, “Purpose,” to replace the phrase “HHS-certified laboratories that licensees and other entities who are subject to this part use for testing urine specimens for validity and the presence of drugs and drug metabolites” with “HHS-certified laboratories that licensees and other entities use to perform testing under this part.” This final rule also revises the title of § 26.153, “Using certified laboratories for testing urine specimens,” by removing the word “urine.” These changes accommodate

the testing of oral fluid specimens at HHS-certified laboratories.

- *Drug testing cutoff levels.* This final rule includes the testing cutoff levels for initial and confirmatory drug testing consistent with Section 3.4 of the 2019 HHS Guidelines for oral fluid testing. This final rule adds a new table to § 26.163(a)(1), for initial testing of oral fluid specimens, and adds a new table to § 26.163(b)(1), for confirmatory drug testing of oral fluid specimens. Each table lists the drugs and drug metabolites and test cutoff levels, and includes footnotes to define substance names such as “Amphetamine (AMP)” and initial testing specifications.

- *Validity testing.* This final rule revises §§ 26.161(b), (d), and (e) to clarify that these validity testing provisions only apply to urine specimens. In § 26.161(b), the phrase “Initial validity testing” is replaced with “Initial validity testing of urine.” In § 26.161(d), the phrase “Results indicating a substituted specimen” is replaced with the phrase “Results indicating a substituted urine specimen.” In § 26.161(e), the phrase “Results indicating a dilute specimen” is replaced with the phrase “Results indicating a dilute urine specimen.” Section 26.31(d)(1) is also revised to remove the word “adulterants” from the “substances tested” list. Including adulterants in the substance list is unnecessary because §§ 26.131 and 26.161 describe each validity test that is to be performed on urine specimens at licensee testing facilities and HHS-certified laboratories, respectively. Adulterant testing is only one of the required validity tests performed on urine specimens. A conforming change is made in this final rule to § 26.405(d), which specifies the required substances that FFD programs for construction must test in specimens. “Adulterants” is removed from the first sentence in § 26.405(d), which describes the substances that licensees and other entities must test for in specimens. Instead, the second sentence in § 26.405(d), “Urine specimens collected for drug testing must be subject to validity testing,” is revised to “Urine specimens collected for drug testing must be subject to validity testing that includes testing for adulterants.” This change clarifies that adulterant testing applies to validity testing of urine specimens.

- *Quality assurance and quality control.* Section 26.167(c) is revised in this final rule to replace the phrase “validity tests” with “validity tests on urine.” Validity testing in 10 CFR part 26 only applies to urine specimens. Section 26.167(d)(1) is revised to

replace the phrase “Any initial drug test performed by an HHS-certified laboratory” with “Any initial drug test of urine performed by an HHS-certified laboratory.”

- *Annual statistical summary reports.* Section 26.169(h) is revised to remove the word “urinalysis” from the phrase “annual statistical summary of urinalysis testing.” This change ensures that the summary of test results provided by the HHS-certified laboratory includes the results for all urine and oral fluid specimens tested for a licensee or other entity.

III. Section-by-Section Analysis

The following paragraphs describe the specific changes within this final rule:

Nomenclature Changes

Throughout 10 CFR part 26, this final rule removes the term “custody and control form” and replaces it with the term “Federal CCF.” This final rule also removes two additional iterations of the term, “custody-and-control forms” and “custody-and-control form(s),” and replaces them with the terms “Federal CCFs” and “Federal CCF(s),” respectively.

Throughout 10 CFR part 26, this final rule replaces the term “chain-of-custody” with the term “chain of custody.”

Section 26.4 FFD Program Applicability to Categories of Individuals

This final rule amends paragraph (e)(6)(iv) to eliminate the phrase “(65 FR 41944; August 9, 2001).”

This final rule revises paragraph (j)(3) to replace the phrase “laboratory certified by the Department of Health and Human Services (HHS)” with “Department of Health and Human Services (HHS)-certified laboratory as defined in § 26.5.”

Section 26.5 Definitions

This final rule adds definitions for *Cancelled test*, *Carryover*, *Certifying Scientist*, *Federal custody and control form*, *Lot*, *Rejected for testing*, and *Responsible Person*. This final rule also revises the definitions for *Calibrator*, *Control*, *Dilute specimen*, *HHS-certified laboratory*, *Invalid result*, *Limit of quantitation*, and *Substituted specimen*.

Section 26.8 Information Collection Requirements: OMB Approval

This final rule amends paragraph (b) to remove the reference to § 26.155.

Section 26.31 Drug and Alcohol Testing

This final rule amends paragraph (b)(2) to eliminate the phrase “(65 FR 41944; August 9, 2001).”

This final rule revises paragraph (d)(1) introductory text to include hydrocodone, hydromorphone, MDMA, MDA, oxycodone, and oxymorphone as substances for which licensees and other entities are required to test in each specimen. The rule also replaces the term “opiates” with the term “opioids,” and removes the term “adulterants.”

This final rule amends paragraph (d)(1)(i)(D) to eliminate the phrase “as specified in § 26.155(a).”

This final rule revises the third sentence of paragraph (d)(1)(ii) to replace the phrase “except if the specimen is dilute and the licensee or other entity has required the HHS-certified laboratory to evaluate the specimen under §§ 26.163(a)(2) or 26.168(g)(3)” with the phrase “except if special analyses of the specimen is performed under § 26.163(a)(2) by the HHS-certified laboratory.”

This final rule revises paragraph (d)(3)(i) to add “urine” to the beginning of the second sentence to read “Urine specimens sent to HHS-certified laboratories must be subject to initial validity and initial drug testing by the laboratory,” and to add a new third sentence to read “Oral fluid specimens sent to HHS-certified laboratories must be subject to initial drug testing by the laboratory.”

Section 26.83 Specimens To Be Collected

This final rule revises paragraph (b) to add to the end of the existing requirement the phrase “unless the licensee or other entity establishes through its policy and procedures that an oral fluid specimen can be collected and tested for any of the observed specimen collection conditions under § 26.115(a)(1) through (3) and (a)(5).” This final rule also revises paragraph (b) to add a new sentence: read “For each observed collection condition under § 26.115(a)(1) through (3) and (a)(5), the licensee or other entity shall always collect and test the same specimen type.”

Section 26.85 Collector Qualifications and Responsibilities

This final rule revises paragraph (a) introductory text to remove “urine” from the first sentence “Urine collector qualifications.” In the second sentence, the final rule replaces the phrase “Urine collectors” with “Each collector” and replaces the words “urine collection

procedures” with the phrase “the collection procedures for each specimen the individual is qualified to collect under this part.” In the third sentence, the final rule replaces the term “Collectors” with “Each collector.”

This final rule revises paragraph (a)(2) to remove the phrase “collections involving ‘shy-bladder’ and attempts to tamper with a specimen.” The final rule adds a new paragraph (a)(2)(i) to specify the “Inability to provide a specimen (e.g., ‘shy bladder’ for a urine specimen, ‘shy lung’ for a breath specimen, dry mouth for an oral fluid specimen),” and a new paragraph (a)(2)(ii) to specify “Attempts to tamper with a specimen.”

This final rule redesignates paragraphs (a)(3) and (4) as paragraphs (a)(4) and (5), respectively, and adds a new paragraph (a)(3). In the renumbered paragraph (a)(5), this final rule replaces the phrase “specimen collection and transfer process” with “specimen collection process,” and adds the phrase “, and the specimen transfer process, if applicable” to the end of the existing requirement.

This final rule removes paragraph (b) and redesignates paragraphs (c), (d), and (e) as paragraphs (b), (c), and (d), respectively. In the redesignated paragraph (b)(1), the final rule replaces the phrase “the requirements of paragraphs (a) and (b) of this section” with the phrase “the requirements of paragraph (a) of this section” as a conforming change.

Section 26.87 Collection Sites

This final rule revises the second sentence of paragraph (a) to replace the phrase “shipping or transportation of urine specimens to a drug testing laboratory; the collection of oral fluids or breath specimens; and the security of alcohol testing devices” with “shipping or transportation of specimens to a drug testing laboratory; the testing of specimens for alcohol; the security of specimen collection and testing devices.”

This final rule revises paragraph (b) to replace the phrase “The collection site must provide for the donor’s visual privacy while the donor and collector are viewing the results of an alcohol test, and for individual privacy while the donor is submitting a urine specimen,” with the sentences “Visual privacy must be provided to the donor and collector when viewing alcohol test results and during the collection of an oral fluid specimen for drug testing. The donor must be provided with individual privacy while the donor is submitting a urine specimen.”

This final rule amends paragraph (f) to replace the term “urine specimen” with “specimen for drug testing.”

This final rule amends paragraph (f)(2) to replace the phrase “If practical, a water coloring agent” with “If practical when a urine specimen is to be collected, a water coloring agent.”

This final rule amends paragraph (f)(3) to replace the phrase “area that will be used for a specimen collection” with “area that will be used for a urine specimen collection.”

This final rule amends paragraph (f)(4) to read “Once the collector has possession of the specimen, if the specimen is urine, the collector shall inspect the toilet bowl and area to ensure that there is no evidence of a subversion attempt and shall then flush the toilet, and for any specimen collected for drug testing, the collector shall instruct the donor to participate with the collector in completing the chain of custody procedures.”

This final rule amends paragraph (f)(5) to replace the phrase “urine specimen” with “specimen for drug testing.”

Section 26.89 Preparing To Collect Specimens for Testing

This final rule amends paragraph (c) to replace the phrase “adulterated, diluted, or adulterated the specimen” with the phrase “adulterated, diluted, or substituted the specimen.”

This final rule revises paragraph (d) to include this phrase at the end of the first sentence: “, except as described in § 26.109(b)(1).” The rule also revises the second sentence in paragraph (d) to replace the phrase “For this purpose, a urine collection procedure is complete when the urine specimen” with the phrase “For the collection of specimen(s) for drug testing, the collection procedure is complete when the specimen”, to replace the phrase “sealed and initialed” with the phrase “sealed with tamper-evident seal, the seal has been dated and initialed”, and to replace the phrase “the chain of custody form has been executed, and the donor has departed the collection site” with the phrase “and the Federal CCF has been completed or when a refusal to test has been determined.”

Section 26.97 Conducting an Initial Test for Alcohol Using a Specimen of Oral Fluids

This final rule revises the section heading to read “Collecting oral fluid specimens for alcohol and drug testing.”

This final rule amends paragraphs (a) introductory text, (a)(4), and (b)(1) through (3), to replace the word “test”

with the phrase “specimen collection” wherever it appears.

This final rule revises paragraph (c)(2) to replace the phrase “initial test using an EBT” with “specimen collection (*i.e.*, initial test using an EBT for alcohol, or urine specimen collection for drug testing).”

This final rule revises paragraph (d) to replace the phrase “The collector shall read the result” with “For alcohol testing of oral fluids, the collector shall read the result.”

Section 26.105 Preparing for Urine Collection

This final rule revises the section heading to “Preparing for the collection of a specimen for drug testing.”

This final rule amends paragraphs (a) and (d) to remove the word “urine” from the phrase “urine specimen” wherever it appears.

This final rule amends paragraph (c) to replace the phrase “wash and dry his or her hands before urinating” with “wash and dry his or her hands before providing a specimen.”

This final rule revises the first sentence of paragraph (e) to change the phrase “sealed collection container from the collection kit materials” to “sealed urine specimen collection container from the collection kit materials or an oral fluid specimen collection device”, and in the second sentence, replaces the phrase “the collection container” with “the urine specimen collection container.”

Section 26.107 Collecting a Urine Specimen

This final rule revises paragraph (b) by redesignating paragraph (b) as paragraph (b)(1) to include the exception provided in § 26.109(b)(1) for a hydration monitor, expand the examples of subversion attempt actions, and add flexibility for other documentation methods. This final rule also adds new paragraph (b)(2) to ensure that if a hydration monitor is used to observe a donor during the § 26.109(b) hydration process, this individual shall immediately inform the collector of any donor conduct that may indicate an attempt to subvert the testing process (*e.g.*, donor leaves the collection site, donor refuses to follow directions).

This final rule adds paragraph (d) to describe the requirements for the actions a collector must take if a refusal to test is determined at any point during the specimen collection process.

Section 26.109 Urine Specimen Quantity

This final rule renames paragraph (b)(1) as introductory text and adds new

paragraphs (b)(1)(i) through (iii) to provide a licensee or other entity with new flexibility in the personnel that may be used to monitor a donor during the hydration process that is initiated when a donor is unable to provide an acceptable quantity of urine during the initial collection attempt (*i.e.*, a shy bladder). For clarity, the last sentence of former paragraph (b)(1) becomes the new first sentence of paragraph (b)(2).

Section 26.111 Checking the Acceptability of the Urine Specimen

This final rule revises paragraph (a) to replace the phrase “greater than 15 mL” with the phrase “equal to or greater than 15 mL” and to add the phrase “(*e.g.*, adulterated or diluted)” after the word “altered.”

This final rule revises the second sentence of paragraph (b) to replace “custody-and-control form” with the phrase “Federal CCF or through another documentation method consistent with the collection procedures of the licensee or other entity” at the end of the existing requirement.

This final rule amends the first sentence of paragraph (c) to remove the word “designated” from the phrase “designated FFD program manager”, and revises the parenthetical phrase in the third sentence to add “(*e.g.*, adulterated or diluted)” after the word “altered”.

This final rule revises paragraph (e) to include the phrase “, except under the conditions described in § 26.107(d)(4)” at the end of the existing requirement, and removes paragraph (f).

Section 26.115 Collecting a Urine Specimen Under Direct Observation

This final rule revises paragraph (a)(3) to replace the phrase “The collector observes conduct clearly and unequivocally indicating an attempt to dilute, substitute, or adulterate the specimen” with the phrase “The collector, or the hydration monitor if one is used as permitted in § 26.109(b)(1), observes conduct by the donor indicating an attempt to subvert the testing process.” Also, this final rule removes the word “and” at the end of paragraph (a)(3). The rule adds paragraph (a)(5) to include an additional instance when an observed collection is required: “The donor requests a retest and either Bottle B or the single specimen is not available due to circumstances outside of the donor’s control, as specified in § 26.165(f)(2).” The rule also replaces the period at the end of the sentence in paragraph (a)(4) with “; or” to accommodate adding a new paragraph (a)(5) in the list of

exclusive grounds for performing a directly observed collection.

This final rule revises the first sentence of paragraph (f) introductory text, “If someone other than the collector is to observe the collection, the collector shall instruct the observer to follow the procedures in this paragraph,” so that it reads “If the observer is not a trained collector, the collector shall, in the presence of the donor, instruct the observer on the collection procedures in paragraph (f)”, and adds it to the end of the existing requirements in paragraph (e).

This final rule revises paragraph (f)(2) to add the following statement to the end of the existing requirement: “A reflective mirror may be used to assist in observing the provision of the specimen only if the physical configuration of the room, stall, or private area used for urination is not sufficient to meet this direct observation requirement; the use of a video camera to assist in the observation process is not permitted.”

This final rule revises paragraph (f)(3) to replace the phrase “If the observer is not the collector, the observer may not take the collection container from the donor, but shall observe the specimen as the donor takes it to the collector” with the phrase “If the observer is not the collector, the observer may not touch or handle the collection container but shall maintain visual contact with the specimen until the donor hands the collection container to the collector.”

This final rule revises paragraph (g) to include the phrase “, and the collector shall follow the procedures in § 26.107(d)” at the end of the existing requirement.

Section 26.117 Preparing Urine Specimens for Storage and Shipping

This final rule revises the section heading to “Preparing drug testing specimens for storage and shipping.”

This final rule revises paragraph (a) to replace the phrase “Both the donor and the collector shall keep the donor’s urine specimen(s) in view” with the phrase “Once the collector is presented with the specimen from the donor, both the donor and the collector shall keep the donor’s specimen(s) in view.”

This final rule revises the first sentence in paragraph (f) to replace the term “chain-of-custody forms” with the term “Federal CCFs” and to replace the phrase “or the licensee’s testing facility,” with the phrase “or to the licensee testing facility.”

This final rule amends paragraph (g) to add the phrase “, except as provided in § 26.109(b)(1)(ii) for the Federal CCF,” to the end of the first sentence.

This final rule amends paragraph (i) to replace the phrase “urine specimen bottle” with “specimen bottle.”

This final rule amends paragraph (j) to replace the word “specimens” with the phrase “urine specimens” and the word “specimen” with the phrase “urine specimen” in the third sentence and to add a new fourth sentence to state that “Oral fluid specimens shall be stored under the conditions specified by the oral fluid specimen collection device manufacturer.”

Section 26.129 Assuring Specimen Security, Chain of Custody, and Preservation

This final rule revises paragraph (b)(1)(ii) to replace the phrase “the specimen may not be tested,” with the phrase “the licensee testing facility shall reject the specimen for testing.”

This final rule revises paragraph (b)(2) introductory text to add the phrase “and report a cancelled test result to the licensee or other entity,” after the phrase “requiring the MRO to cancel the testing of a donor’s urine specimen.”

Section 26.133 Cutoff Levels for Drugs and Drug Metabolites

This final rule revises the introductory text to clarify that the specified cutoff level must be used to determine whether the specimen is negative or positive for the indicated drugs or drug metabolites being tested. The rule also revises the table heading to “Table 1 to § 26.133—Urine, Initial Test Cutoff Levels for Drugs and Drug Metabolites” and the column header “Drug or metabolites” to “Drugs or drug metabolites” to align with the table heading. The rule further revises the table to (1) lower the initial test cutoff level for cocaine metabolites from 300 ng/mL to 150 ng/mL, (2) replace “opiate metabolites” with “codeine/morphine” and include a new footnote 1 to clarify the existing requirement that morphine is the target analyte for codeine/morphine testing, (3) add initial testing for hydrocodone and hydromorphone at a cutoff level of 300 ng/mL, (4) add initial testing for oxycodone and oxymorphone at a cutoff level of 100 ng/mL, (5) add the drug class “Opioids:” to appear above the listing for “codeine/morphine,” (6) add initial testing for 6-AM at a cutoff level of 10 ng/mL, (7) lower the initial test cutoff level for amphetamines (abbreviated in the table as AMP) from 1000 ng/mL to 500 ng/mL, (8) include a new table footnote 2 regarding initial test kits, (9) include a new table footnote 3 to clarify that for amphetamines testing, methamphetamine (abbreviated in the table as MAMP) is the target analyte,

(10) add initial testing for MDMA and MDA at a cutoff level of 500 ng/mL, and (11) provide the full chemical name for MDMA and MDA in new footnotes 4 and 5 to the table, respectively.

Section 26.137 Quality Assurance and Quality Control

This final revises paragraph (d)(5) to remove the phrase “that appears to be a donor specimen to the licensee testing facility technicians.”

This final rule revises paragraph (e)(6) introductory text to replace the phrase “A minimum of 10 percent of all specimens in each analytical run” at the start of the first sentence with the phrase “A minimum of 10 percent of the total specimens in each analytical run” and adds the parenthetical phrase “(i.e., calibrators and controls)” after the phrase “quality control samples.” The rule also replaces the word “drugs” in the first sentence and the phrase “drug and metabolite” in the second sentence with the phrases “drugs and drug metabolites” and “drug and drug metabolite,” respectively.

This final rule revises paragraph (e)(6)(i) to replace the phrase “Sample(s) certified by an HHS-certified laboratory to contain no drugs or drug metabolites (i.e., negative urine samples)” with the phrase “At least one control certified by an HHS-certified laboratory to contain no drug or drug metabolite.”

This final rule revises paragraph (e)(6)(ii) to replace the phrase “drug(s) or drug metabolite(s)” with the phrase “the drug or drug metabolite.”

This final rule revises paragraph (e)(6)(iii) to replace the phrase “the drug(s) or drug metabolite(s) targeted at 25 percent below the cutoff” with the phrase “the drug or drug metabolite targeted at 75 percent of the cutoff.”

This final rule removes paragraph (e)(6)(v).

Section 26.151 Purpose

This final rule revises the purpose of Subpart G, “Laboratories Certified by the Department of Health and Human Services,” to read “This subpart contains requirements for the HHS-certified laboratories that licensees and other entities use to perform testing under this part.”

Section 26.153 Using Certified Laboratories for Testing Urine Specimens

This final rule revises the section heading to read “Using certified laboratories for testing specimens.”

This final rule revises paragraph (a) to replace the phrase “laboratories certified under the Department of Health and Human Services (HHS)

Mandatory Guidelines for Federal Workplace Drug Testing Programs [published in the **Federal Register** on April 11, 1988 (53 FR 11970), and as amended, June 9, 1994 (59 FR 29908), November 13, 1998 (63 FR 63483), and April 13, 2004 (69 FR 19643)]” with the phrase “HHS-certified laboratories as defined in § 26.5.” The rule also removes the sentence “Information concerning the current certification status of laboratories is available from the Division of Workplace Programs, Center for Substance Abuse Prevention, Substance Abuse and Mental Health Services Administration, Room 815, 5600 Fishers Lane, Rockwall 2 Bldg., Rockville, Maryland 20857.”

This final rule revises paragraph (g) to replace the term “Federal custody-and-control form” with “Federal CCF” and the term “non-Federal form” with “non-Federal CCF.”

Section 26.155 Laboratory Personnel

This final rule removes and reserves § 26.155.

Section 26.157 Procedures

This final rule revises paragraph (a) to replace the phrase “clear and well-documented procedures for” with the phrase “procedures specific to this part that document the” and to remove “urine” in the phrase “testing of urine specimens.”

This final rule removes and reserves paragraph (b) and removes paragraphs (c) through (e).

Section 26.159 Assuring Specimen Security, Chain of Custody, and Preservation

This final rule revises paragraph (b)(1)(ii) to replace the phrase “the specimens may not be tested and the licensee or entity shall” with the phrase “the laboratory shall reject the specimens for testing. The licensee or other entity shall.”

This final rule revises paragraph (b)(2) introductory text to add after “The following are exclusive grounds requiring the MRO to cancel the testing of a donor’s urine specimen,” the phrase “and report a cancelled test to the licensee or other entity.”

This final rule revises the second sentence of paragraph (c) to replace the term “custody-and-control” with the term “chain of custody.”

This final rule revises paragraph (d) to replace the term “custody-and-control” with the term “chain of custody.”

This final rule revises paragraph (e) to replace the term “custody-and-control” with the term “chain of custody” in the two instances that it occurs in the paragraph.

Section 26.161 Cutoff Levels for Validity Testing

This final rule amends paragraph (b) introductory text to replace the phrase “Initial validity testing” with the phrase “Initial validity testing of urine.”

This final rule amends paragraphs (c)(3) through (6) to replace all instances of “LOD” with “LOQ.”

This final rule revises paragraph (c)(5) to replace the phrase “GC/MS for the confirmatory test” with the phrase “a different confirmatory method (e.g., gas chromatography/mass spectrometry (GC/MS)).”

This final rule revises paragraph (c)(6) to replace the phrase “GC/MS for the confirmatory test” with the phrase “a different confirmatory method (e.g., GC/MS).”

This final rule amends paragraph (d) to replace the phrase “Results indicating a substituted specimen,” with the phrase “Results indicating a substituted urine specimen.”

This final rule amends paragraph (e) to replace the phrase “Results indicating a dilute specimen,” with the phrase “Results indicating a dilute urine specimen.”

This final rule amends paragraphs (f)(5) and (7) to replace all instances of the term “LOD” with the term “LOQ.”

This final rule revises the first sentence of paragraph (h) to replace “More stringent validity test cutoff levels are prohibited” with “Validity test cutoff levels.” The final rule also revises the second sentence to replace the phrase “may not specify more stringent cutoff levels” with “may use more stringent cutoff levels”, and the phrase “only if testing is performed at an HHS-certified laboratory” is added to the end of the sentence.

Section 26.163 Cutoff Levels for Drug and Drug Metabolites

This final rule revises paragraph (a)(1) introductory text to replace the phrase “negative for the indicated drugs and drug metabolites” with the phrase “negative or positive for the indicated drugs and drug metabolites” and revise the phrase “except if validity testing indicates that the specimen is dilute” to read “except as specified in paragraph (a)(2) of this section.”

This final rule revises the table heading in paragraph (a)(1) to “Table 1 to paragraph (a)(1)–Urine, Initial Test Cutoff Levels for Drugs and Drug Metabolites” and the column header “Drug or metabolites” in Table 1 to “Drugs or drug metabolites” to align with the table heading. This final rule further revises the initial test cutoff level table for urine testing to (1) lower

the initial test cutoff level for cocaine metabolites from 300 ng/mL to 150 ng/mL, (2) replace “opiate metabolites” with “codeine/morphine” and include a new footnote 1 to clarify the existing requirement that morphine is the target analyte for codeine/morphine testing, (3) add initial testing for hydrocodone and hydromorphone at a cutoff level of 300 ng/mL, (4) add initial testing for oxycodone and oxymorphone at a cutoff level of 100 ng/mL, (5) add the drug class “Opioids:” to appear above the listing for “codeine/morphine,” (6) add initial testing for 6-AM at a cutoff level of 10 ng/mL, (7) lower the initial test cutoff level for amphetamines (abbreviated in the table as AMP) from 1000 ng/mL to 500 ng/mL, (8) include a new footnote 2 regarding initial test kits, (9) include a new footnote 3 to clarify that for amphetamines testing, methamphetamine (abbreviated in the table as MAMP) is the target analyte, (10) add initial testing for MDMA and MDA at a cutoff level of 500 ng/mL, and (11) provide the full chemical names for MDMA and MDA in new footnotes 4 and 5 to the table, respectively.

This final rule adds a second table to paragraph (a)(1) titled “Table 2 to paragraph (a)(1)–Oral Fluid, Initial Test Cutoff Levels for Drugs and Drug Metabolites.” Table 2 lists each drug and drug metabolite and the cutoff level for initial testing of oral fluid specimens. The table includes the following substances and associated cutoff levels in nanograms (ng) per milliliter (mL): (1) “marijuana (THC)” at 4 ng/mL; (2) “cocaine/benzoyllecgonine” at 15 ng/mL; (3) the drug class “opioids” is listed; (4) “codeine/morphine” at 30 ng/mL; (5) “hydrocodone/hydromorphone” at 30 ng/mL; (6) “oxycodone/oxymorphone” at 30 ng/mL; (7) “6-acetylmorphine (6-AM)” at 4 ng/mL, (8) “phencyclidine (PCP)” at 10 ng/mL; (9) the drug class “amphetamines” is listed; (10) “AMP/MAMP” at 50 ng/mL; and (11) “MDMA/MDA” at 50 ng/mL. The table includes five footnotes. Footnote 1 is for column header “Cutoff level [nanograms (ng/mL)]” and describes the requirements for grouped analytes testing. Footnote 2 is for the substance “marijuana (THC)” and describes the target analyte for this testing. Footnote 3 is assigned to the cutoff level for 6-acetylmorphine and describes the alternate technology testing requirements. Footnote 4 presents the full chemical names for AMP (amphetamine) and (MAMP) methamphetamine because the table includes the acronyms for clarity of presentation. Footnote 5 presents the full chemical names for MDMA

(methylenedioxymethamphetamine) and MDA (methylenedioxyamphetamine) because the table includes the acronyms for clarity of presentation.

This final rule revises paragraph (a)(2) introductory text to remove the phrase “At the licensee’s or other entity’s discretion, as documented in the FFD program policies and procedures, the licensee or other entity may require the HHS-certified laboratory to conduct special analyses of dilute specimens” and replace it with the phrase “HHS-certified laboratories shall conduct special analyses of specimens.”

This final rule revises paragraph (a)(2)(i) to add the phrase “, or if a specimen is collected under direct observation for any of the conditions specified in § 26.115(a)(1) through (3) or (a)(5),” after the phrase “If initial validity testing indicates that a specimen is dilute.” The rule also revises paragraph (a)(2)(i) to replace the phrase “the HHS-certified laboratory shall compare the responses of the dilute specimen to the cutoff calibrator in each of the drug classes” with the phrase “the laboratory shall compare the immunoassay responses of the specimen to the cutoff calibrator in each drug class tested.”

This final rule revises paragraph (a)(2)(ii) to state “If any immunoassay response is equal to or greater than 40 percent of the cutoff calibrator, the laboratory shall conduct confirmatory drug testing of the specimen to the LOQ for those drugs and/or drug metabolites; and.”

This final rule revises paragraph (b)(1) introductory text to replace the phrase “except if the licensee or other entity requires the special analysis of dilute specimens as permitted in paragraph (a)(2)” with the phrase “except as permitted in paragraph (a)(2).”

This final rule revises the table heading in paragraph (b)(1) to read “Table 3 to paragraph (b)(1)–Urine, Confirmatory Test Cutoff Levels for Drugs and Drug Metabolites” and the column header “Drug or metabolites” in the initial test cutoff level table for urine testing to read “Drugs or drug metabolites.” The final rule further revises the initial test cutoff level table for urine testing to (1) lower the confirmatory test cutoff level for cocaine metabolite from 150 ng/mL to 100 ng/mL, (2) revise “Opiates” to read “Opioids,” (3) add confirmatory testing for hydrocodone, hydromorphone, oxycodone, and oxymorphone at a cutoff level of 100 ng/mL, (4) remove footnote 3 regarding the requirement that confirmatory testing of 6-AM only proceed when confirmatory testing

shows a morphine concentration exceeding 2000 ng/mL, (5) lower the confirmatory test cutoff levels for amphetamine and methamphetamine from 500 ng/mL to 250 ng/mL, (6) redesignate footnote 4 as footnote 3 and revise the text to lower the concentration of amphetamine that must be present in the specimen from 200 ng/mL to 100 ng/mL, and (7) add confirmatory testing for MDMA and MDA at a cutoff level of 250 ng/mL.

This final rule adds another new table to paragraph (b)(1) titled “Table 4 to paragraph (b)(1)—Oral Fluid, Confirmatory Test Cutoff Levels for Drugs and Drug Metabolites.” Table 4 lists each drug and drug metabolite and the cutoff level for confirmatory testing of the substance in oral fluid. The table includes the following substances and associated cutoff levels in ng/mL: (1) “marijuana (THC)” at 2 ng/mL; (2) “cocaine” and “benzoylecgonine” each at 8 ng/mL; (3) the drug class “opioids” is listed; (4) “codeine” and “morphine” each at 15 ng/mL; (5) “hydrocodone,” “hydromorphone,” “oxycodone,” and “oxymorphone” each at 15 ng/mL; (6) 6-acetylmorphine (6-AM) at 2 ng/mL, (7) “phencyclidine (PCP)” at 10 ng/mL; (8) the drug class “amphetamines” is listed; and (9) “amphetamine,” “methamphetamine,” “MDMA,” and “MDA” each at 25 ng/mL.

Section 26.165 Testing Split Specimens and Retesting Single Specimens

This final rule adds a new fifth sentence to paragraph (b)(2) that states, “The MRO shall document in his or her records when (*i.e.*, date and time) the request was received from the donor to retest an aliquot of the single specimen or to test the Bottle B split specimen.”

This final rule deletes the first sentence in paragraph (b)(3) and revises the second sentence to state “No entity, other than the MRO as permitted in § 26.185(l), may order the retesting of an aliquot of the single specimen or the testing of the Bottle B split specimen.”

This final rule revises the last sentence in paragraph (f)(1) introductory text by adding the phrase “the MRO shall report a cancelled test result to the licensee or other entity, and” to indicate that the MRO must report the cancelled test.

This final rule revises paragraph (f)(2) to add: (1) instruction for the MRO to “report a cancelled test result to the licensee or other entity for the donor’s specimen”; (2) instruction for the licensee or other entity that “the donor shall receive no notice of the collection requirement before he or she is instructed to proceed to the collection

site”; (3) that the “licensee or other entity shall continue to administratively withdraw the individual’s authorization, as required by § 26.165(f)(1) until the results of the second collection have been received by the MRO”; and (4) a reference to §§ 26.129(b)(2) and 26.159(b)(2), which describes the circumstances that require the MRO to cancel a test result.

Section 26.167 Quality Assurance and Quality Control

This final rule amends paragraph (c) to replace the phrase “validity tests” with “validity tests on urine.”

This final rule amends paragraph (d)(1) to replace the phrase “Any initial drug test performed by an HHS-certified laboratory” with “Any initial drug test of urine performed by an HHS-certified laboratory.”

This final rule revises paragraph (d)(3)(i) to replace the phrase “Sample(s) certified to contain no drugs or drug metabolites (*i.e.*, negative urine samples)” with the phrase “At least one control certified to contain no drug or drug metabolite.”

This final rule revises paragraph (d)(3)(ii) to replace the phrase “a drug(s) or drug metabolite(s)” with the phrase “the drug or drug metabolite.”

This final rule revises paragraph (d)(3)(iii) to replace the phrase “a drug(s) or drug metabolite(s) targeted at 25 percent below the cutoff” with the phrase “the drug or drug metabolite targeted at 75 percent of the cutoff.”

This final rule revises paragraph (d)(4) to add the parenthetical statement “(*i.e.*, calibrators and controls)” after the phrase “quality control samples.”

This final rule revises paragraph (e)(2) to replace the phrase “At least 10 percent of the samples in each analytical run of specimens must be calibrators and controls” with the phrase “A minimum of 10 percent of the total specimens in each analytical run must be quality control samples (*i.e.*, calibrators and controls).”

This final rule revises paragraph (e)(3)(i) to replace the phrase “Sample(s) certified to contain no drug (*i.e.*, negative urine samples)” with the phrase “At least one control certified to contain no drug or drug metabolite.”

This final rule revises paragraph (e)(3)(ii) to replace the phrase “Positive calibrator(s) and control(s) with a drug(s) or drug metabolite(s)” with the phrase “A calibrator with its drug concentration at the cutoff.”

This final rule revises paragraph (e)(3)(iii) to replace the phrase “a drug(s) or drug metabolite(s)” with the phrase “the drug or drug metabolite.”

This final rule revises paragraph (e)(3)(iv) to replace the phrase “At least one calibrator or control that is targeted” with the phrase “At least one control targeted.”

This final rule amends paragraph (f)(3) to correct the capitalization of the “r” and the “p” in the position title in the phrase “the laboratory’s responsible person” to “Responsible Person.”

Section 26.168 Blind Performance Testing

This final rule revises paragraph (h)(1) to remove the phrase “, and for no more than 6 months” from this requirement.

Section 26.169 Reporting Results

This final rule amends paragraph (a) to correct the capitalization of the “c” and the “s” in the position title in the phrase “the laboratory’s certifying scientist” to “Certifying Scientist.”

This final rule amends paragraph (c)(2) to remove the word “opiate” from the phrase “confirmatory opiate test results for morphine or codeine.”

This final rule amends paragraph (h) introductory text to remove the word “urinalysis” from the phrase “annual statistical summary of urinalysis testing.”

This final rule also makes conforming changes to the names of the drugs and drug metabolites listed in paragraph (h)(3) to include adding “(as THCA)” after “Marijuana metabolite” in paragraph (h)(3)(i); adding “(as benzoylecgonine)” after “Cocaine metabolite” in paragraph (h)(3)(ii); revising “Opiates (total)” to “Opioids (total)” in paragraph (h)(3)(iii) introductory text; removing “and” in paragraph (h)(3)(iii)(B); revising 6-AM to “6-acetylmorphine (6-AM)” in paragraph (h)(3)(iii)(C); adding new paragraphs (h)(3)(iii)(D) through (G) to add hydrocodone, hydromorphone, oxycodone, and oxymorphone to the list of opioid test results; and revising “Phencyclidine” to “Phencyclidine (PCP)” in paragraph (h)(3)(iv).

This final rule revises paragraph (h)(3)(v) to add new paragraphs (h)(3)(v)(C) and (D) to add “Methylenedioxymethamphetamine (MDMA) and “Methylenedioxyamphetamine (MDA)” to the list of amphetamines test results.

Section 26.183 Medical Review Officer

This final rule revises paragraphs (c) introductory text, (c)(1), and (d)(2)(ii) to remove the phrase “at the licensee’s or other entity’s discretion.”

Section 26.185 Determining a Fitness-for-Duty Policy Violation

This final rule redesignates paragraph (f)(3) as paragraph (f)(4) and adds a new paragraph (f)(3) to state that if the MRO and the laboratory agree that further testing would not be useful and there is no legitimate technical or medical explanation for an invalid urine specimen test result based on a pH result in the range of 9.0 to 9.5, the MRO shall consider whether there is evidence of elapsed time, exposure of the specimen to high temperature, or both that could account for the pH value. If the MRO obtains objective and sufficient information regarding elapsed time, temperature conditions, or both to conclude that an acceptable explanation exists for the invalid test result due to pH, the MRO would direct the licensee or other entity to collect a second urine specimen from the donor as soon as reasonably practicable. This second specimen may not be collected from the donor under direct observation conditions.

This final rule amends paragraph (g)(1) to replace the phrase “paragraph (g)(4)” with the phrase “paragraph (g)(3).”

This final rule revises paragraph (g)(2) introductory text to replace the phrase “If the licensee or other entity requires the HHS-certified laboratory to conduct the special analysis of dilute specimens permitted by § 26.163(a)(2), the results of the special analysis are positive,” with the phrase “If the results of the special analysis testing required by § 26.163(a)(2) are positive.” The rule also revises paragraph (g)(2) to replace the phrase “under paragraph (g)(4)” with the phrase “under paragraph (g)(3).”

This final rule revises paragraph (g)(2)(iii) to remove the phrase “clearly and unequivocally.”

This final rule removes paragraph (g)(3).

This final rule redesignates paragraphs (g)(4) and (5) as paragraphs (g)(3) and (4), respectively. The rule amends newly redesignated paragraph (g)(3) to replace the phrase “any opium, opiate, or opium derivative (e.g., morphine and/or codeine)” with “opioids (i.e., morphine and/or codeine).”

This final rule revises paragraph (j) introductory text to replace “opiates” with “opioids” and to correct an editorial error in the first sentence.

This final rule revises the first sentence of paragraph (j)(1) to replace “opiates” with “opioids (i.e., morphine and/or codeine)”, and to replace the phrase “opium, an opiate, or an opium

derivative (e.g., morphine/codeine)” with “morphine and/or codeine.”

This final rule amends paragraph (j)(2) to replace “opiates” with “opioids”.

This final rule amends paragraph (j)(3) to replace “opiates” with “opioids (i.e., morphine and/or codeine).”

This final rule amends paragraph (j)(4) to replace “opiates” with “opioids.”

Section 26.405 Drug and Alcohol Testing

This final rule revises paragraph (d) to add hydrocodone, hydromorphone, MDMA, MDA, oxycodone, and oxymorphone as substances for which licensees and other entities are required to test in each specimen. The term “opiates” is also replaced with the term “opioids.”

The rule also removes the term “adulterants” from the first sentence in paragraph (d), which describes the substances that licensees and other entities must test for in specimens. Instead, the final rule revises the second sentence “Urine specimens collected for drug testing must be subject to validity testing” to “Urine specimens collected for drug testing must be subject to validity testing that includes testing for adulterants.”

Section 26.415 Audits

This final rule amends paragraph (c) to eliminate the phrase “(65 FR 41944; August 9, 2001).”

Section 26.715 Recordkeeping Requirements for Collection Sites, Licensee Testing Facilities, and Laboratories Certified by the Department of Health and Human Services

This final rule amends paragraph (b)(1) to replace the phrase “collection site, licensee testing facility, or HHS-certified laboratory” with the phrase “collection site or licensee testing facility.”

Section 26.717 Fitness-for-Duty Program Performance Data

This final rule revises paragraph (b)(3) to replace the phrase “(i.e., individuals in applicant status, permanent licensee employees, C/Vs),” with the phrase “(i.e., licensee and other entity employees, C/Vs).”

This final rule revises paragraph (b)(4) to replace the phrase “(i.e., individuals in applicant status, permanent licensee employees, C/Vs),” with the phrase “(i.e., licensee and other entity employees, C/Vs).”

IV. Regulatory Flexibility Certification

Under the Regulatory Flexibility Act (5 U.S.C. 605(b)), the NRC certifies that this rule will not have a significant economic impact on a substantial number of small entities. This final rule affects the licensing and operation of nuclear power plants and Category I fuel cycle facilities. The companies that own these facilities do not fall within the scope of the definition of “small entities” set forth in the Regulatory Flexibility Act or the size standards established by the NRC (§ 2.810).

The NRC estimates that none of the 59 entities affected by the rule fall within the scope of the definition of “small entities” set forth in the Regulatory Flexibility Act or the size standards established by the NRC (§ 2.810). Therefore, the rule does not impact a substantial number of small entities.

The NRC requested comment on the proposed rule and accompanying regulatory analysis on the impact of the proposed rule on small entities. The NRC received no comment submissions from an identified small entity.

V. Regulatory Analysis

The NRC has prepared a regulatory analysis on this regulation. The analysis examines the costs and benefits of the alternatives considered by the NRC. The regulatory analysis is available as indicated in the “Availability of Documents” section of this document.

VI. Backfitting and Issue Finality

The Commission has completed a backfitting and issue finality assessment for this final rule under §§ 50.109, “Backfitting,” 52.98, “Finality of combined licenses; information requests,” and 70.76, “Backfitting.” This final rule constitutes backfitting for current holders of operating licenses and construction permits for power reactors under 10 CFR part 50, “Domestic licensing of production and utilization facilities,” and renewed licenses under 10 CFR part 54, “Requirements for renewal of operating licenses for nuclear power plants,” and under § 70.76(a)(1) for applicable current 10 CFR part 70 licensees. This final rule affects the issue finality accorded to current holders of combined licenses under § 52.98. This final rule is being imposed as a cost-justified substantial increase in the overall protection of the public health and safety or common defense and security. The bases for this determination are presented in the backfit and issue finality assessment, which is available as indicated in the “Availability of Documents” section of this document.

Regulatory Guidance

As explained in Regulatory Guide (RG) 5.89, “Fitness-for-Duty Programs for Commercial Power Reactor and Category I Special Nuclear Material Licensees,” applicants and licensees are not required to comply with the positions set forth in RG 5.89. Therefore, issuance of RG 5.89 does not constitute backfitting, as that term is defined in § 50.109 and as described in NRC Management Directive 8.4, “Management of Backfitting, Forward Fitting, Issue Finality, and Information Requests,” or affect the issue finality of any approval issued under 10 CFR part 52.

VII. Cumulative Effects of Regulation

Cumulative Effects of Regulation (CER) consists of the challenges licensees may face in addressing the implementation of new regulatory positions, programs, and requirements (e.g., rulemaking, guidance, generic letters, backfits, inspections). The CER may manifest in several ways, including the total burden imposed on licensees by the NRC from simultaneous or consecutive regulatory actions that can adversely affect the licensee’s capability to implement those requirements, while continuing to operate or construct its facility in a safe and secure manner.

The goals of the NRC’s CER effort were met throughout the development of this final rule. The NRC engaged external stakeholders at public meetings and by soliciting public comments on the proposed rule and associated draft guidance document. The proposed rule and draft guidance (84 FR 48750) were issued on September 16, 2019, for public comment. A public meeting was held on November 7, 2019, to discuss the proposed rule and draft guidance. A public meeting on implementation was held on April 13, 2021. Summaries of both meetings are available in ADAMS, as provided in the “Availability of Documents” section of this document. The feedback from the April 13, 2021, public meeting informed the NRC’s final rule implementation schedule.

Based upon input from the public and affected licensees, the NRC has established a compliance deadline for the requirements in this final rule of 1 year from the date of publication of this final rule in the **Federal Register**. See the **DATES** section of this document.

VIII. Plain Writing

The Plain Writing Act of 2010 (Pub. L. 111–274) requires Federal agencies to write documents in a clear, concise, and well-organized manner. The NRC has written this document to be consistent

with the Plain Writing Act as well as the Presidential Memorandum, “Plain Language in Government Writing,” published June 10, 1998 (63 FR 31885).

IX. Environmental Impact: Categorical Exclusion

The NRC has determined that this final rule is the type of action described under § 51.22(c)(1). Therefore, neither an environmental impact statement nor an environmental assessment has been prepared for this final rule.

X. Paperwork Reduction Act Statement

This final rule contains new or amended collections of information subject to the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*). The collections of information were approved by the Office of Management and Budget (OMB), control number 3150–0146.

The burden to the public for the information collections is estimated to average 0.8 hours per response for information collection requirements contained in 10 CFR part 26, including the time for reviewing instructions, searching existing data sources, gathering and maintaining data needed, and completing and reviewing the information collections.

The information collection contained in 10 CFR part 26 is impacted by the revision of existing and addition of new requirements to align the NRC’s drug testing requirements more closely with updates made to the HHS Guidelines. The NRC updated the drug testing panel and lowered the testing cutoff levels for some drugs tested, which impacts the existing information collections contained in 10 CFR part 26, because additional individuals will likely test positive for drugs. Additional positive test results will increase the costs associated with the recordkeeping and reporting requirements applicable to licensees and other entities. In addition, the NRC is including new information collection requirements in §§ 26.107(d), 26.157(a), 26.165(b)(2), 26.165(f)(1) and 26.185(f)(3). This information will be used by the NRC to uniformly address subversion attempts identified at the collection site (§ 26.107(d)), clarify that HHS-certified laboratories are to maintain testing procedures specific to 10 CFR part 26 (§ 26.157(a)), permit the MRO to initiate retesting of a donor specimen upon receiving an oral request from the donor and maintaining a record of receiving that request (§ 26.165(b)(2)), document the existing process that the MRO is to report a cancelled test result to the licensee or other entity if the results of specimen retesting fail to confirm the test results

from the initial laboratory (§ 26.165(f)(1)), and establish procedures to review invalid specimen test results due to high pH values (§ 26.165(f)(3)). In addition, the NRC updated NRC Form 890, “Single Positive Test Form,” and NRC Form 891, “Annual Reporting Form for Drug and Alcohol Tests,” to reflect the requirements of this final rule. Confidential and proprietary information submitted to the NRC is protected in accordance with NRC regulations at §§ 9.17(a) and 2.390(b).

You may submit comments on any aspect of the information collections, including suggestions for reducing the burden, by the following methods:

- *Federal rulemaking website:* Go to <https://www.regulations.gov> and search for Docket ID NRC–2009–0225.

- *Mail comments to:* FOIA, Library, and Information Collections Branch, Office of the Chief Information Officer, Mail Stop: T6–A10M, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001, or by email to Infocollects.Resource@nrc.gov, and to the OMB reviewer at: OMB Office of Information and Regulatory Affairs (3150–0146), Attn: Desk Officer for the Nuclear Regulatory Commission, 725 17th Street, NW Washington, DC 20503; email: oira_submission@omb.eop.gov.

Public Protection Notification

The NRC may not conduct or sponsor, and a person is not required to respond to, a request for information unless the document requesting or requiring the collection displays a currently valid OMB control number.

XI. Congressional Review Act

This final rule is a rule as defined in the Congressional Review Act (5 U.S.C. 801–808). However, the Office of Management and Budget has not found it to be a major rule as defined in the Congressional Review Act.

XII. Criminal Penalties

For the purposes of Section 223 of the Atomic Energy Act of 1954, as amended (AEA), the NRC is issuing this final rule that will amend §§ 26.4, 26.31, 26.83, 26.85, 26.87, 26.89, 26.97, 26.105, 26.107, 26.109, 26.111, 26.115, 26.117, 26.129, 26.133, 26.137, 26.153, 26.155, 26.157, 26.159, 26.161, 26.163, 26.165, 26.167, 26.168, 26.169, 26.183, 26.185, 26.405, 26.415, 26.717 under one or more of Sections 161b, 161i, or 161o of the AEA. Willful violations of the rule would be subject to criminal enforcement. Criminal penalties as they apply to regulations in 10 CFR part 26 are discussed in § 26.825, “Criminal penalties.”

XIII. Compatibility of Agreement State Regulations

Under the “Agreement State Program Policy Statement” approved by the Commission on October 2, 2017, and published in the **Federal Register** (82 FR 48535; October 18, 2017), this rule is classified as compatibility “NRC.” Compatibility is not required for Category “NRC” regulations. The NRC program elements in this category are those that relate directly to areas of regulation reserved to the NRC by the AEA or the provisions of 10 CFR, and although an Agreement State may not adopt program elements reserved to the NRC, it may wish to inform its licensees of certain requirements via a mechanism that is consistent with the particular State’s administrative procedure laws but does not confer regulatory authority on the State.

XIV. Voluntary Consensus Standards

The National Technology Transfer and Advancement Act of 1995, Public Law 104–113, requires that Federal agencies use technical standards that are developed or adopted by voluntary consensus standards bodies unless the

use of such a standard is inconsistent with applicable law or otherwise impractical. In this final rule, the NRC updated and enhanced the consistency of 10 CFR part 26 with the HHS Guidelines; improving the effectiveness and efficiency of FFD programs with regard to drug testing; and improving clarity in the organization and language of the rule. This action does not constitute the establishment of a voluntary consensus standard that contains generally applicable requirements.

XV. Availability of Guidance

The NRC is issuing new guidance, Regulatory Guide 5.89, “Fitness-for-Duty Programs for Commercial Power Reactor and Category I Special Nuclear Material Licensees,” to support the implementation of the requirements in this final rule. New RG 5.89 is publicly available in ADAMS under Accession No. ML20143A034. Information and public comment submissions related to the guidance can be accessed by searching on the Federal e-Rulemaking website, <https://www.regulations.gov>, under Docket ID NRC–2009–0225. The

associated draft regulatory guide (DG–5040) was published for public comment in conjunction with the proposed rule. The final guidance reflects public comments received on the draft regulatory guide. The NRC’s response to the public comments on this guidance is available in ADAMS, as provided in the “Availability of Documents” section of this document.

Regulatory Guide 5.89 describes methods that the NRC considers acceptable for complying with some of the changes in this final rule. For example, guidance is provided concerning monitoring of a donor during the 3-hour hydration period, use of reflective mirrors for directly observed collections, use of a same-gender observer other than the collector during a directly observed collection, and MRO review of invalid test results due to high pH.

XVI. Availability of Documents

The documents identified in the following table are available to interested persons through one or more of the following methods, as indicated.

Document	ADAMS accession No./Federal Register citation
1988 HHS Guidelines—Final Guidelines (April 11, 1988)	53 FR 11970
1994 HHS Guidelines—Revised Mandatory Guidelines (June 9, 1994)	59 FR 29908
1998 HHS Guidelines—Revised Mandatory Guidelines (November 13, 1998)	63 FR 63483
2004 HHS Guidelines—Notice of Proposed Revisions to Mandatory Guidelines (April 13, 2004)	69 FR 19673
2004 HHS Guidelines—Revised Mandatory Guidelines (April 13, 2004)	69 FR 19643
2008 HHS Guidelines—Revised Mandatory Guidelines (November 25, 2008)	73 FR 71858
2008 HHS Guidelines—Revised Mandatory Guidelines, Correction of Effective Date (December 10, 2008)	73 FR 75122
2008 HHS Guidelines—Revised Mandatory Guidelines, Change in Effective Date (April 30, 2010)	75 FR 22809
2015 HHS Guidelines—Notice of Proposed Revisions to Mandatory Guidelines (May 15, 2015)	80 FR 28101
2017 HHS Guidelines—Revised Mandatory Guidelines (January 23, 2017)	82 FR 7920
HHS “Medical Review Officer Manual for Federal Workplace Drug Testing Programs,” effective October 1, 2017, revised March 2018.	ML21119A058
2019 HHS Guidelines—Issuance of Mandatory Guidelines for Federal Workplace Drug Testing Programs—Oral/Fluid (October 25, 2019).	84 FR 57554
2019 NRC 10 CFR Part 26 Proposed Rule (September 16, 2019)	84 FR 48750
1989 NRC 10 CFR Part 26 Final Rule (June 7, 1989)	54 FR 24468
1993 NRC 10 CFR Part 26 Final Rule (June 3, 1993)	58 FR 31467
2008 NRC 10 CFR Part 26 Final Rule (March 31, 2008)	73 FR 16966
2009 NRC 10 CFR Part 26 Final Rule, Correcting Amendment (August 3, 2009)	74 FR 38326
Policy Statement on Adequacy and Compatibility of Agreement State Programs (September 3, 1997)	62 FR 46517
Presidential Memorandum, “Plain Language in Government Writing” (June 10, 1998)	63 FR 31885
2001 DOT 49 CFR Part 40 Final Rule, Procedures for Transportation Workplace Drug and Alcohol Testing Programs, Technical Amendments (August 9, 2001).	66 FR 41944
2010 DOT 49 CFR Part 40 Final Rule, Procedures for Transportation Workplace Drug and Alcohol Testing Programs (August 16, 2010).	75 FR 49850
2017 DOT 49 CFR Part 40 Final Rule, Procedures for Transportation Workplace Drug and Alcohol Testing Program: Addition of Certain Schedule II Drugs to the Department of Transportation’s Drug-Testing Panel and Certain Minor Amendments (November 13, 2017).	82 FR 52229
Commission Policy Statement on Fitness for Duty of Nuclear Power Plant Personnel (August 4, 1986)	51 FR 27921
Cook J.D., Strauss K.A., Caplan Y.H., LoDico C.P., and Bush D.M. (2007), “Urine pH: The Effects of Time and Temperature After Collection,” <i>Journal of Analytical Toxicology</i> , Vol. 31, 486–496.	https://academic.oup.com/jat/article/31/8/486/757830
Executive Order 12564, Drug-free Federal Workplace (September 17, 1986)	51 FR 32889
Key Substance Use and Mental Health Indicators in the United States: Results from the 2019 National Survey on Drug Use and Health (NSDUH) (September 2020), HHS Publication Number PEP20–07–01–001.	ML21166A009
NRC Draft Regulatory Guide DG–5040, “Urine Specimen Collection and Test Result Review under 10 CFR Part 26, ‘Fitness for Duty Programs’” (August 2019).	ML19116A077

Document	ADAMS accession No./Federal Register citation
NRC Enforcement Guidance Memorandum—Dispositioning Violations of NRC Requirements for Initial Validity and Drug Tests at Licensee Testing Facilities (EGM-09-003) (March 31, 2009).	ML090760728
NRC Management Directive 8.4, “Management of Backfitting, Forward Fitting, Issue Finality, and Information Requests” (September 20, 2019).	ML18093B087
NRC Backfitting and Issue Finality Assessment for the 10 CFR Part 26 Fitness for Duty Drug Testing Requirements Final Rule (November 2022).	ML22133A046
NRC Public Meeting Summary and Meeting Materials (October 11, 2011)	ML112930153
NRC Public Meeting Summary (November 7, 2019)	ML19336A003
NRC Public Meeting Summary (April 13, 2021)	ML21096A015
NRC Regulatory Analysis for the 10 CFR Part 26 Fitness for Duty Drug Testing Requirements Final Rule (November 2022).	ML22133A044
NRC Regulatory Analysis Guidelines, NUREG/BR-0058, Draft Revision 5 (February 2020)	ML19261A277
NRC Regulatory Basis: Proposed Rulemaking to Amend 10 CFR Part 26, “Fitness for Duty Programs,” based on Select Provisions of the 2008 HHS Guidelines (May 10, 2013).	ML13066A703
NRC Regulatory Guide 5.89, “Fitness-for-Duty Programs for Commercial Power Reactor and Category I Special Nuclear Material Licensees” (November 1, 2022).	ML20143A034
NRC Responses to Public Comments (November 2022)	ML22133A052
NRC Report “Summary of Fitness for Duty Program Performance Reports for Calendar Year 2013” (September 3, 2014) ..	ML14246A440
NRC Report “Summary of Fitness for Duty Program Performance Reports for Calendar Year 2015” (November 13, 2017)	ML17313A337
Paperwork Reduction Act Statement: 10 CFR Part 26, Fitness for Duty Programs, Information Collections Contained in Fitness for Duty Drug Testing Requirements Final Rule (October 19, 2022).	ML21111A046
Quest Diagnostics (2011). Impacts of Panel Changes—The First Three Months (January 25, 2011)	ML19169A153
Quest Diagnostics (2012). Cocaine Positives Spike 33% After New Government Rule for Safety-Sensitive Workers (March 13, 2012).	ML19169A156
Quest Diagnostics (2014). Workforce Drug Test Positivity Rate Increases for the First Time in 10 Years, Driven by Marijuana and Amphetamines, Finds Quest Diagnostics Drug Testing Index™ Analysis of Employment Drug Tests (Press Release and Drug Testing Index, 2014 Report) (September 11, 2014).	ML19169A147

The NRC may post materials related to this document, including public comments, on the Federal rulemaking website at <https://www.regulations.gov> under Docket ID NRC-2009-0225. In addition, the Federal rulemaking website allows members of the public to receive alerts when changes or additions occur in a docket folder. To subscribe: (1) navigate to the docket folder (NRC-2009-0225); (2) click the “Subscribe” link; and (3) enter an email address and click on the “Subscribe” link.

List of Subjects in 10 CFR Part 26

Administrative practice and procedure, Alcohol abuse, Alcohol testing, Appeals, Chemical testing, Drug abuse, Drug testing, Employee assistance programs, Fitness for duty, Management actions, Nuclear power plants and reactors, Privacy, Protection of information, Radiation protection, Reporting and recordkeeping requirements.

For the reasons set out in the preamble and under the authority of the Atomic Energy Act of 1954, as amended; the Energy Reorganization Act of 1974, as amended; and 5 U.S.C. 552 and 553, the NRC is adopting the following amendments to 10 CFR part 26:

PART 26—FITNESS FOR DUTY PROGRAMS

■ 1. The authority citation for part 26 continues to read as follows:

Authority: Atomic Energy Act of 1954, secs. 53, 103, 104, 107, 161, 223, 234, 1701 (42 U.S.C. 2073, 2133, 2134, 2137, 2201, 2273, 2282, 2297f); Energy Reorganization Act of 1974, secs. 201, 202 (42 U.S.C. 5841, 5842); 44 U.S.C. 3504 note.

■ 2. In part 26, wherever they may occur:

- a. Remove the term “custody-and-control form” and add in its place the term “Federal CCF”;
- b. Remove the term “custody-and-control forms” and add in its place the term “Federal CCFs”;
- c. Remove the term “custody-and-control form(s)” and add in its place the term “Federal CCF(s)”;
- d. Remove the phrase “chain-of-custody” and add in its place the phrase “chain of custody”.

■ 3. In § 26.4:

- a. In paragraph (e)(6)(iv), remove “(65 FR 41944; August 9, 2001)”;
- b. Revise paragraph (j)(3).

The revision reads as follows:

§ 26.4 FFD program applicability to categories of individuals.

* * * * *

(j) * * *

(3) Urine specimens are tested for validity and the presence of drugs and drug metabolites at a Department of Health and Human Services (HHS)-certified laboratory, as defined in § 26.5;

* * * * *

■ 4. In § 26.5:

- a. Revise the definition of “Calibrator”;

- b. Add in alphabetical order definitions for “Cancelled test”, “Carryover”, and “Certifying Scientist”;
- c. Revise the definitions of “Control” and “Dilute specimen”;
- d. Add in alphabetical order a definition for “Federal custody and control form (Federal CCF)”;
- e. Revise the definitions of “HHS-certified laboratory”, “Invalid result”, and “Limit of quantitation”;
- f. Adding in alphabetical order definitions for “Lot”, “Rejected for testing”, and “Responsible Person”; and
- g. Revising the definition of “Substituted specimen”.

The revisions and additions read as follows:

§ 26.5 Definitions.

* * * * *

Calibrator means a solution of known concentration in the appropriate matrix that is used to define expected outcomes of a measurement procedure or to compare the response obtained with the response of a donor specimen or quality control sample. The concentration of the analyte of interest in the calibrator is known within limits ascertained during its preparation.

Cancelled test means the test result reported by the MRO to the licensee or other entity when a specimen has been reported to the MRO by the HHS-certified laboratory as an invalid result (for which the donor has no legitimate explanation), a specimen has been rejected for testing by the licensee

testing facility or HHS-certified laboratory, or the retesting of a single specimen or the testing of Bottle B of a split specimen fails to reconfirm the original test result. For alcohol testing only, *cancelled test* means a test result that was not acceptable because testing did not meet the quality assurance and quality control requirements in § 26.91.

Carryover means the effect that occurs when a test result has been affected by a preceding sample or specimen during analysis.

Certifying Scientist means the individual at an HHS-certified laboratory responsible for verifying the chain of custody and scientific reliability of any test result reported by an HHS-certified laboratory.

* * * * *

Control means a sample used to evaluate whether an analytical procedure or test is operating within predefined tolerance limits.

* * * * *

Dilute specimen means a urine specimen with creatinine and specific gravity values that are lower than expected but are still within the physiologically producible ranges of human urine.

* * * * *

Federal custody and control form (Federal CCF) means any HHS-approved form, which has not expired, that is published in the **Federal Register** and is used to document the collection, custody, transport, and testing of a specimen.

* * * * *

HHS-certified laboratory means a laboratory that is certified to meet the standards of the *Mandatory Guidelines for Federal Workplace Drug Testing Programs* (the HHS Guidelines) at the time that testing of a specimen is performed for a licensee or other entity and performs that testing for a licensee or other entity in accordance with the HHS Guidelines, unless otherwise specified in this part.

* * * * *

Invalid result means the result reported by an HHS-certified laboratory in accordance with the criteria established in § 26.161(f) when a positive, negative, adulterated, or substituted result cannot be established for a specific drug or specimen validity test.

* * * * *

Limit of quantitation (LOQ) means for quantitation assays, the lowest concentration at which the identity and concentration of the analyte can be accurately established.

Lot means a number of units of an item (e.g., drug test kits, reagents,

quality control samples) manufactured from the same starting materials within a specified period of time for which the manufacturer states that the items have essentially the same performance characteristics and the same expiration date.

* * * * *

Rejected for testing means the result reported to the MRO by a licensee testing facility or HHS-certified laboratory when no tests can be performed on a specimen.

* * * * *

Responsible Person means the person at the HHS-certified laboratory who assumes professional, organizational, educational, and administrative responsibility for the day-to-day management of the HHS-certified laboratory.

* * * * *

Substituted specimen means a specimen that has been submitted in place of the donor's urine, as evidenced by creatinine and specific gravity values that are outside the physiologically producible ranges of human urine.

* * * * *

§ 26.8 [Amended]

■ 5. In § 26.8, in paragraph (b), remove the reference “26.155”.

■ 6. In § 26.31:

■ a. In paragraph (b)(2), remove the phrase “(65 FR 41944; August 9, 2001)”;

■ b. Revise paragraph (d)(1) introductory text;

■ c. In paragraph (d)(1)(i)(D), remove the phrase “, as specified in § 26.155(a)”;

■ d. In paragraph (d)(1)(ii), revise the third sentence; and

■ e. In paragraph (d)(3)(i), revise the second sentence and add a new third sentence.

The addition and revisions read as follows:

§ 26.31 Drug and alcohol testing.

* * * * *

(d) * * *

(1) *Substances tested*. At a minimum, licensees and other entities shall test for marijuana metabolite, cocaine metabolite, opioids (codeine, morphine, 6-acetylmorphine, hydrocodone, hydromorphone, oxycodone, and oxymorphone), amphetamines (amphetamine, methamphetamine, methylenedioxymethamphetamine, and methylenedioxyamphetamine), phencyclidine, and alcohol.

* * * * *

(ii) * * * Test results that fall below the established cutoff levels may not be considered when determining appropriate action under subpart D of

this part, except if special analyses of the specimen is performed under § 26.163(a)(2) by the HHS-certified laboratory. * * *

* * * * *

(3) * * *

(i) * * * Urine specimens sent to HHS-certified laboratories must be subject to initial validity and initial drug testing by the laboratory. Oral fluid specimens sent to HHS-certified laboratories must be subject to initial drug testing by the laboratory. * * *

* * * * *

■ 7. In § 26.83, revise paragraph (b) to read as follows:

§ 26.83 Specimens to be collected.

* * * * *

(b) Collect only urine specimens for both initial and confirmatory tests for drugs, unless the licensee or other entity establishes through its policy and procedures that an oral fluid specimen can be collected and tested for any of the observed specimen collection conditions under § 26.115(a)(1) through (3) and (5). For each observed collection condition under § 26.115(a)(1) through (3) and (5), the licensee or other entity shall always collect and test the same specimen type.

■ 8. In § 26.85:

■ a. Revise paragraphs (a) introductory text and (a)(2);

■ b. Redesignate paragraphs (a)(3) and (4) as paragraphs (a)(4) and (5), respectively, and add new paragraph (a)(3);

■ c. In newly redesignated paragraph (a)(5), remove the phrase “collection and transfer process” and add in its place the phrase “collection process”, and add at the end of the paragraph the phrase “, and the specimen transfer process, if applicable”;

■ d. Remove paragraph (b) and redesignate paragraphs (c) through (e) as paragraphs (b) through (d), respectively; and

■ e. In newly redesignated paragraph (b)(1), remove “paragraphs (a) or (b)” and add in its place “paragraph (a)”.

The revisions and addition read as follows:

§ 26.85 Collector qualifications and responsibilities.

* * * * *

(a) *Collector qualifications*. Each collector shall be knowledgeable of the requirements of this part and the FFD policy and procedures of the licensee or other entity for whom collections are performed, and shall keep current on any changes to the collection procedures for each specimen the individual is qualified to collect under

this part. Each collector shall receive qualification training that meets the requirements of this paragraph and demonstrate proficiency in applying the requirements of this paragraph before serving as a collector. At a minimum, qualification training must provide instruction on the following subjects:

* * * * *

(2) Methods to address “problem” collections, including, but not limited to:

(i) Inability to provide a specimen (e.g., “shy bladder” for a urine specimen, “shy lung” for a breath specimen, dry mouth for an oral fluid specimen); and

(ii) Attempts to tamper with a specimen;

(3) Operation of the particular specimen collection or alcohol testing device(s) (e.g., alcohol screening device (ASD), EBT, oral fluid) to be used, consistent with the most recent version of the manufacturers’ instructions;

* * * * *

■ 9. In § 26.87:

■ a. Revise the second sentence in paragraph (a) and revise paragraph (b);

■ b. In paragraph (f) introductory text, remove the phrase “collect a urine specimen” and add in its place the phrase “collect a specimen for drug testing”;

■ c. In paragraph (f)(2), remove the phrase “If practical, a water coloring agent” and add in its place the phrase “If practical when a urine specimen is to be collected, a water coloring agent”;

■ d. In paragraph (f)(3), remove the phrase “area that will be used for specimen collection” and add in its place the phrase “the area that will be used for a urine specimen collection”;

■ e. Revise paragraph (f)(4); and

■ f. In paragraph (f)(5), in the first sentence, remove the phrase “urine specimen” and add in its place the phrase “specimen for drug testing”.

The revisions read as follows:

§ 26.87 Collection sites.

(a) * * * Each collection site must provide for the collection, security, temporary storage, and shipping or transportation of specimens to a drug testing laboratory; the testing of specimens for alcohol; the security of specimen collection and testing devices; and test results. * * *

(b) Visual privacy must be provided to the donor and collector when viewing alcohol test results and during the collection of an oral fluid specimen for drug testing. The donor must be provided with individual privacy while submitting a urine specimen, except if a directly observed urine specimen

collection is required. Unauthorized personnel may not be present for the specimen collection.

* * * * *

(f) * * *

(4) Once the collector has possession of the specimen, if the specimen is urine, the collector shall inspect the toilet bowl and area to ensure that there is no evidence of a subversion attempt and shall then flush the toilet, and for any specimen collected for drug testing, the collector shall instruct the donor to participate with the collector in completing the chain of custody procedures.

* * * * *

■ 10. In § 26.89:

■ a. In paragraph (c), remove the words “adulterated, diluted, or adulterated the specimen” and add in their place the words “adulterated, diluted, or substituted the specimen”; and

■ b. Revise paragraph (d).

The revision reads as follows:

§ 26.89 Preparing to collect specimens for testing.

* * * * *

(d) In order to promote the security of specimens, avoid distraction of the collector, and ensure against any confusion in the identification of specimens, a collector shall conduct only one collection procedure at any given time, except as described in § 26.109(b)(1). For the collection of specimen(s) for drug testing, the collection procedure is complete when the specimen container has been sealed with a tamper-evident seal, the seal has been dated and initialed, and the Federal CCF has been completed or when a refusal to test has been determined.

■ 11. In § 26.97:

■ a. Revise the section heading;

■ b. In paragraphs (a) introductory text, (a)(4), and (b)(1) through (3), wherever it appears, remove the word “test” and add in its place the phrase “specimen collection”; and

■ c. Revise paragraph (c)(2), and the first sentence in paragraph (d).

The revisions read as follows:

§ 26.97 Collecting oral fluid specimens for alcohol and drug testing.

* * * * *

(c) * * *

(2) Immediately conduct another specimen collection (*i.e.*, initial test using an EBT for alcohol, or urine specimen collection for drug testing).

(d) For alcohol testing of oral fluids, the collector shall read the result displayed on the device no sooner than

the device’s manufacturer instructs.

* * *

* * * * *

■ 12. In § 26.105:

■ a. Revise the section heading;

■ b. In paragraph (a), wherever it appears, remove the word “urine”;

■ c. In paragraph (c), remove the phrase “wash and dry his or her hands before urinating” and add in its place the phrase “wash and dry his or her hands before providing a specimen”;

■ d. In paragraph (d), remove the word “urine”; and

■ e. Revise paragraph (e).

The revisions read as follows:

§ 26.105 Preparing for the collection of a specimen for drug testing.

* * * * *

(e) The collector may select, or allow the donor to select, an individually wrapped or sealed urine specimen collection container from the collection kit materials or an oral fluid specimen collection device. Either the collector or the donor, with both present, shall unwrap or break the seal of the urine specimen collection container. With the exception of the collection container, the donor may not take anything from the collection kit into the room or stall used for urination.

■ 13. In § 26.107, revise paragraph (b) and add paragraph (d) to read as follows:

§ 26.107 Collecting a urine specimen.

* * * * *

(b)(1) The collector shall pay careful attention to the donor during the entire collection process, except as provided in § 26.109(b)(1), to observe any conduct that indicates an attempt to subvert the testing process (e.g., tampering with a specimen; having a substitute urine specimen in plain view; attempting to bring an adulterant, urine substitute, heating element, and/or temperature measurement device into the room, stall, or private area used for urination). If any such conduct is detected, the collector shall document a description of the conduct on the Federal CCF or through another documentation method consistent with the collection procedures of the licensee or other entity, and contact FFD program management to determine whether a directly observed collection is required, as described in § 26.115.

(2) If a hydration monitor is used to observe a donor during the § 26.109(b)(1) hydration process, this individual shall immediately inform the collector of any donor conduct that may indicate an attempt to subvert the testing process (e.g., donor leaves the

collection site, donor refuses to follow instructions).

* * * * *

(d) If a refusal to test is determined at any point during the specimen collection process, the collector shall do the following:

- (1) Inform the donor that a refusal to test has been determined;
- (2) Terminate the collection process;
- (3) Document a description of the refusal to test on the Federal CCF or through another documentation method consistent with the collection procedures of the licensee or other entity;
- (4) Discard any urine specimen(s) provided by the donor, unless the specimen was collected for a post-event test under § 26.31(c)(3); and
- (5) Immediately inform the FFD program manager.

■ 14. In § 26.109, revise paragraph (b)(1) and add a new first sentence to paragraph (b)(2) to read as follows:

§ 26.109 Urine specimen quantity.

* * * * *

(b) * * *

(1) The collector shall encourage the donor to drink a reasonable amount of liquid (normally, 8 ounces of water every 30 minutes, but not to exceed a maximum of 40 ounces over 3 hours) until the donor provides a specimen of at least 30 mL. Alternatively, as specified in the licensee's or other entity's FFD program procedures, the collector may assign responsibility for monitoring a donor during the hydration process to another collector who meets the requirements in § 26.85(a) or to a hydration monitor. If another collector or hydration monitor is used, the collector:

- (i) Shall explain the hydration process and acceptable donor behavior to the hydration monitor;
- (ii) Shall record the name of the other collector or hydration monitor on the Federal CCF; and
- (iii) May perform other collections while the donor is in the hydration process;

(2) The collector shall provide the donor with a separate collection container for each successive specimen.

* * *

* * * * *

■ 15. In § 26.111:

- a. Revise paragraph (a) and the second sentence in paragraph (b);
- b. In paragraph (c), the first sentence, remove the word "designated" and revise the third sentence;
- c. Revise paragraph (e); and
- d. Remove paragraph (f).

The revisions read as follows:

§ 26.111 Checking the acceptability of the urine specimen.

(a) Immediately after the donor provides the urine specimen to the collector, including specimens of less than 30 mL but equal to or greater than 15 mL, the collector shall measure the temperature of the specimen. The temperature-measuring device used must accurately reflect the temperature of the specimen and not contaminate the specimen. The time from urination to temperature measurement may not exceed 4 minutes. If the temperature of a urine specimen is outside the range of 90 °F to 100 °F (32 °C to 38 °C), that is a reason to believe the donor may have altered (e.g., adulterated or diluted) or substituted the specimen.

(b) * * * The collector shall note any unusual findings on the Federal CCF or through another documentation method consistent with the collection procedures of the licensee or other entity.

(c) * * * In addition, the collector shall inform the donor that he or she may volunteer to submit a second specimen under direct observation to counter the reason to believe the donor may have altered (e.g., adulterated or diluted) or substituted the specimen.

* * * * *

(e) As much of the suspect specimen as possible must be preserved, except under the conditions described in § 26.107(d)(4).

■ 16. In § 26.115:

- a. Republish paragraph (a) introductory text, revise paragraphs (a)(3) and (4), and add paragraph (a)(5);
- b. Revise paragraph (e);
- c. Revise paragraph (f) introductory text, republish paragraph (f)(1), and revise paragraphs (f)(2) and (3); and
- d. Revise paragraph (g).

The republications, revisions, and addition read as follows:

§ 26.115 Collecting a urine specimen under direct observation.

(a) Procedures for collecting urine specimens must provide for the donor's privacy unless directed by this subpart or the MRO or FFD program manager determines that a directly observed collection is warranted. The following circumstances constitute the exclusive grounds for performing a directly observed collection:

* * * * *

(3) The collector, or the hydration monitor if one is used as permitted in § 26.109(b)(1), observes conduct by the donor indicating an attempt to subvert the testing process;

(4) A directly observed collection is required under § 26.69; or

(5) The donor requests a retest and either Bottle B or the single specimen is not available due to circumstances outside of the donor's control, as described in § 26.165(f)(2).

* * * * *

(e) The collector shall ensure that the observer is the same gender as the donor. A person of the opposite gender may not act as the observer under any conditions. The observer may be a different person from the collector and need not be a qualified collector. If the observer is not a qualified collector, the collector shall, in the presence of the donor, instruct the observer on the collection procedures in paragraph (f) of this section before proceeding with the directly observed collection.

(f) The individual who observes the collection shall follow these procedures:

(1) The observer shall instruct the donor to adjust his or her clothing to ensure that the area of the donor's body between the waist and knees is exposed;

(2) The observer shall watch the donor urinate into the collection container. Specifically, the observer shall watch the urine go from the donor's body into the collection container. A reflective mirror may be used to assist in observing the provision of the specimen only if the physical configuration of the room, stall, or private area used for urination is not sufficient to meet this direct observation requirement; the use of a video camera to assist in the observation process is not permitted;

(3) If the observer is not the collector, the observer may not touch or handle the collection container but shall maintain visual contact with the specimen until the donor hands the collection container to the collector; and

* * * * *

(g) If a donor declines to allow a directly observed collection that is required or permitted under this section, the donor's refusal constitutes an act to subvert the testing process, and the collector shall follow the procedures in § 26.107(d).

* * * * *

■ 17. In § 26.117:

- a. Revise the section heading;
- b. In paragraph (a), revise the first sentence and republish the second sentence;
- c. Revise the first sentence in paragraph (f);
- d. In paragraph (g), at the end of the first sentence, add the phrase "except as provided in § 26.109(b)(1)(ii) for the Federal CCF";
- e. In paragraph (i), remove the words "urine specimen bottle" and add in

their place the words “specimen bottle”; and

■ f. In paragraph (j) remove the phrase “Specimens that have not been shipped” and add in their place the phrase “Urine specimens that have not shipped”; remove phrase “any specimen” and add in its place the phrase “any urine specimen”; and add a new fourth sentence.

The revisions, republication, and addition read as follows:

§ 26.117 Preparing drug testing specimens for storage and shipping.

(a) Once the collector is presented with the specimen from the donor, both the donor and the collector shall keep the donor’s specimen(s) in view at all times before the specimen(s) are sealed and labeled. If any specimen or aliquot is transferred to another container, the collector shall ask the donor to observe the transfer and sealing of the container with a tamper-evident seal.

* * * * *

(f) The specimens and Federal CCFs must be packaged for transfer to the HHS-certified laboratory or to the licensee testing facility. * * *

* * * * *

(j) * * * Oral fluid specimens shall be stored under the conditions specified by the oral fluid specimen collection device manufacturer. * * *

* * * * *

■ 18. In § 26.129, revise paragraphs (b)(1)(ii) and (b)(2) introductory text to read as follows:

§ 26.129 Assuring specimen security, chain of custody, and preservation.

* * * * *

(b) * * *

(1) * * *

(ii) If there is reason to believe that the integrity or identity of a specimen is in question (as a result of tampering or discrepancies between the information on the specimen bottle and on the accompanying Federal CCFs that cannot be resolved), the licensee testing facility shall reject the specimen for testing. The licensee or other entity shall ensure that another collection occurs as soon as reasonably practical, except if a split specimen collection was performed, either the Bottle A or Bottle B seal remains intact, and the intact specimen contains at least 15 mL of urine. In this instance, the licensee testing facility shall forward the intact specimen for testing to the HHS-certified laboratory and may not conduct any testing at the licensee testing facility.

(2) The following are exclusive grounds requiring the MRO to cancel the testing of a donor’s urine specimen

and report a cancelled test result to the licensee or other entity:

* * * * *

■ 19. Revise § 26.133 to read as follows:

§ 26.133 Cutoff levels for drugs and drug metabolites.

Subject to the provisions of § 26.31(d)(3)(iii), licensees and other entities may specify more stringent cutoff levels for drugs and drug metabolites than those in Table 1 to § 26.133 and, in such cases, may report initial test results for only the more stringent cutoff levels. Otherwise, the following cutoff levels must be used for initial testing of urine specimens to determine whether they are negative or positive for the indicated drugs and drug metabolites:

TABLE 1 TO § 26.133—URINE, INITIAL TEST CUTOFF LEVELS FOR DRUGS AND DRUG METABOLITES

Drugs or drug metabolites	Cutoff level [nanograms (ng)/mL]
Marijuana metabolites	50
Cocaine metabolites	150
Opioids:	
Codeine/Morphine ¹	2,000
Hydrocodone/Hydromorphone	300
Oxycodone/Oxymorphone	100
6-acetylmorphine (6-AM)	10
Phencyclidine (PCP)	25
Amphetamines: ²	
AMP/MAMP ³	500
MDMA ⁴ /MDA ⁵	500

¹ Morphine is the target analyte for codeine/morphine testing.

² Either a single initial test kit or multiple initial test kits may be used provided the single test kit detects each target analyte independently at the specified cutoff.

³ Methamphetamine (MAMP) is the target analyte for amphetamine (AMP)/MAMP testing.

⁴ Methylenedioxymethamphetamine.

⁵ Methylenedioxymphetamine.

■ 20. In § 26.137,

■ a. Revise paragraphs (d)(5), (e)(6) introductory text, and (e)(6)(i) through (iii); and

■ b. Remove paragraph (e)(6)(v).

The revisions read as follows:

§ 26.137 Quality assurance and quality control.

* * * * *

(d) * * *

(5) Each analytical run performed to conduct initial validity testing shall include at least one quality control sample.

* * * * *

(e) * * *

(6) A minimum of 10 percent of the total specimens in each analytical run of specimens to be initially tested for drugs and drug metabolites by the licensee testing facility must be quality control samples (*i.e.*, calibrators and controls),

which the licensee testing facility shall use for internal quality control purposes. (These samples are not forwarded to the HHS-certified laboratory for further testing, other than for performance testing of the samples.) Licensee testing facilities shall ensure that quality control samples that are positive for each drug and drug metabolite for which the FFD program conducts testing are included in at least one analytical run each calendar quarter. The quality control samples for each analytical run must include—

(i) At least one control certified by an HHS-certified laboratory to contain no drug or drug metabolite;

(ii) At least one positive control with the drug or drug metabolite targeted at 25 percent above the cutoff;

(iii) At least one positive control with the drug or drug metabolite targeted at 75 percent of the cutoff;

* * * * *

■ 21. Revise § 26.151 to read as follows:

§ 26.151 Purpose.

This subpart contains requirements for the HHS-certified laboratories that licensees and other entities use to perform testing under this part.

■ 22. In § 26.153, revise the section heading and paragraphs (a) and (g) to read as follows:

§ 26.153 Using certified laboratories for testing specimens.

(a) Licensees and other entities who are subject to this part shall use only HHS-certified laboratories as defined in § 26.5.

* * * * *

(g) If licensees or other entities use a form other than the current Federal CCF, licensees and other entities shall provide a memorandum to the laboratory explaining why a non-Federal CCF was used, but must ensure, at a minimum, that the form used contains all the required information on the Federal CCF.

§ 26.155 [Removed and Reserved]

■ 23. Remove and reserve § 26.155.

■ 24. In § 26.157, revise paragraph (a), remove and reserve paragraph (b), and remove paragraphs (c) through (e) and the undesignated paragraph at the end.

The revision reads as follows:

§ 26.157 Procedures.

(a) HHS-certified laboratories shall develop, implement, and maintain procedures specific to this part that document the accession, receipt, shipment, and testing of specimens.

* * * * *

■ 25. In § 26.159, revise paragraphs (b)(1)(ii) and (b)(2) introductory text, the second sentence in paragraph (c), and paragraphs (d) and (e) to read as follows:

§ 26.159 Assuring specimen security, chain of custody, and preservation.

* * * * *

(b) * * *

(1) * * *

(ii) If the licensee or other entity has reason to question the integrity and identity of the specimens, the laboratory shall reject the specimens for testing. The licensee or other entity shall ensure that another collection occurs as soon as reasonably practical, except if a split specimen collection was performed, either the Bottle A or Bottle B seal remains intact, and the intact specimen contains at least 15 mL of urine. In this instance, if the licensee testing facility has retained the specimen in Bottle B, the licensee testing facility shall forward the intact specimen for testing to the HHS-certified laboratory and may not conduct any testing at the licensee testing facility.

(2) The following are exclusive grounds requiring the MRO to cancel the testing of a donor's urine specimen and report a cancelled test to the licensee or other entity:

* * * * *

(c) * * * Laboratory personnel shall use aliquots and laboratory internal chain of custody forms when conducting initial and confirmatory tests. * * *

(d) The laboratory's internal chain of custody form must allow for identification of the donor and documentation of the testing process and transfers of custody of the specimen.

(e) Each time a specimen is handled or transferred within the laboratory, laboratory personnel shall document the date and purpose on the chain of custody form and every individual in the chain shall be identified. Authorized technicians are responsible for each urine specimen or aliquot in their possession and shall sign and complete chain of custody forms for those specimens or aliquots as they are received.

* * * * *

■ 26. In § 26.161:

■ a. In paragraph (b) introductory text, remove the phrase "Initial validity testing" and add in its place the phrase "Initial validity testing of urine";

■ b. In paragraphs (c)(3) and (4), wherever it appears, remove the term "LOD" and add in its place the term "LOQ";

■ c. Revise paragraphs (c)(5) and (6);

■ d. Revise the headings for paragraphs (d) and (e);

■ e. In paragraphs (f)(5) and (7), wherever it appears, remove the term "LOD" and add in its place the term "LOQ"; and

■ f. Revise paragraph (h).

The revisions read as follows:

§ 26.161 Cutoff levels for validity testing.

* * * * *

(c) * * *

(5) The presence of glutaraldehyde is verified using either an aldehyde test (aldehyde present) or the specimen yields the characteristic immunoassay response on one or more drug immunoassay tests for the initial test on the first aliquot and a different confirmatory test (e.g., gas chromatography/mass spectrometry (GC/MS)) for the confirmatory test with the glutaraldehyde concentration equal to or greater than the LOQ of the analysis on the second aliquot;

(6) The presence of pyridine (pyridinium chlorochromate) is verified using either a general oxidant colorimetric test (with a cutoff equal to or greater than 200 mcg/mL nitrite-equivalents or a cutoff equal to or greater than 50 mcg/mL chromium (VI)-equivalents) or a chromium (VI) colorimetric test (chromium (VI) concentration equal to or greater than 50 mcg/mL) for the initial test on the first aliquot and a different confirmatory test (e.g., GC/MS) for the confirmatory test with the pyridine concentration equal to or greater than the LOQ of the analysis on the second aliquot;

* * * * *

(d) *Results indicating a substituted urine specimen.* * * *

(e) *Results indicating a dilute urine specimen.* * * *

* * * * *

(h) *Validity test cutoff levels.*

Licensees and other entities may use more stringent cutoff levels for validity tests than those specified in this section only if the testing is performed at an HHS-certified laboratory.

■ 27. In § 26.163:

■ a. Republish the paragraph (a) heading;

■ b. Revise paragraph (a)(1);

■ c. Revise paragraph (a)(2) introductory text and (a)(2)(i) and (ii);

■ d. Republish the paragraph (b) heading; and

■ e. Revise paragraph (b)(1).

The republications and revisions read as follows:

§ 26.163 Cutoff levels for drugs and drug metabolites.

(a) *Initial drug testing.* (1) HHS-certified laboratories shall apply the following cutoff levels for initial testing of specimens to determine whether they are negative or positive for the indicated drugs and drug metabolites, except as specified in paragraph (a)(2) of this section or the licensee or other entity has established more stringent cutoff levels:

**TABLE 1 TO PARAGRAPH (a)(1)—
URINE, INITIAL TEST CUTOFF LEVELS
FOR DRUGS AND DRUG METABO-
LITES**

Drugs or drug metabolites	Cutoff level [nanograms (ng)/mL]
Marijuana metabolites	50
Cocaine metabolites	150
Opioids:	
Codeine/Morphine ¹	2,000
Hydrocodone/Hydromorphone	300
Oxycodone/Oxymorphone	100
6-acetylmorphine (6-AM)	10
Phencyclidine (PCP)	25
Amphetamines: ²	
AMP/MAMP ³	500
MDMA ⁴ /MDA ⁵	500

¹ Morphine is the target analyte for codeine/morphine testing.

² Either a single initial test kit or multiple initial test kits may be used provided the single test kit detects each target analyte independently at the specified cutoff.

³ Methamphetamine (MAMP) is the target analyte for amphetamine (AMP)/MAMP testing.

⁴ Methylenedioxymethamphetamine.

⁵ Methylenedioxymphetamine.

TABLE 2 TO PARAGRAPH (a)(1)—ORAL FLUID, INITIAL TEST CUTOFF LEVELS FOR DRUGS AND DRUG METABOLITES

Drugs or drug metabolites	Cutoff level ¹ [nanograms (ng)/mL]
Marijuana (THC) ^{2,3}	4
Cocaine/Benzoyllecgonine	15
Opioids:	
Codeine/Morphine	30
Hydrocodone/Hydromorphone	30
Oxycodone/Oxymorphone	30
6-acetylmorphine (6-AM)	4 ³
Phencyclidine (PCP)	10
Amphetamines:	
AMP/MAMP ⁴	50
MDMA/MDA ⁵	50

¹ For grouped analytes (*i.e.*, two or more analytes in the same drug class with the same initial test cutoff):

• Immunoassay: The test must be calibrated with one analyte from the group identified as the target analyte. The cross reactivity of the immunoassay to the other analyte(s) within the group must be 80 percent or greater; if not, separate immunoassays must be used for the analytes within the group.

• Alternative technology: Either one analyte or all analytes from the group must be used for calibration, depending on the technology. At least one analyte within the group must have a concentration equal to or greater than the initial test cutoff or, alternatively, the sum of the analytes present.

² An immunoassay must be calibrated with the target analyte, delta-9-tetrahydrocannabinol (THC).

³ Alternate technology (THC and 6-AM): The confirmatory tests cutoff must be used for an alternate technology initial test that is specific for the target analyte (*i.e.*, 2 ng/mL for THC, 2 ng/mL for 6-AM).

⁴ Amphetamine (AMP) and methamphetamine (MAMP).

⁵ Methylenedioxymethamphetamine (MDMA) and methylenedioxyamphetamine (MDA).

(2) HHS-certified laboratories shall conduct special analyses of specimens as follows:

(i) If initial validity testing indicates that a specimen is dilute, or if a specimen is collected under direct observation for any of the conditions specified in § 26.115(a)(1) through (3) or (a)(5), the laboratory shall compare the immunoassay responses of the specimen to the cutoff calibrator in each drug class tested;

(ii) If any immunoassay response is equal to or greater than 40 percent of the cutoff calibrator, the laboratory shall conduct confirmatory drug testing of the specimen to the LOQ for those drugs and/or drug metabolites; and

* * * * *

(b) *Confirmatory drug testing.* (1) A specimen that is identified as positive on an initial drug test must be subject to confirmatory testing for the class(es) of drugs for which the specimen initially tested positive. The HHS-certified laboratory shall apply the confirmatory cutoff levels specified in this paragraph, except as permitted in paragraph (a)(2) of this section or the licensee or other entity has established more stringent cutoff levels.

TABLE 3 TO PARAGRAPH (b)(1)—URINE, CONFIRMATORY TEST CUTOFF LEVELS FOR DRUGS AND DRUG METABOLITES

Drugs or drug metabolites	Cutoff level (ng/mL)
Marijuana metabolite ¹	15
Cocaine metabolite ²	100
Opioids:	
Morphine	2,000
Codeine	2,000
Hydrocodone	100
Hydromorphone	100
Oxycodone	100
Oxymorphone	100
6-acetylmorphine (6-AM)	10
Phencyclidine (PCP)	25
Amphetamines:	
Amphetamine	250
Methamphetamine ³	250
Methylenedioxymethamphetamine (MDMA)	250
Methylenedioxyamphetamine (MDA)	250

¹ As delta-9-tetrahydrocannabinol-9-carboxylic acid (THCA).

² As benzoyllecgonine.

³ To be reported positive for methamphetamine, a specimen must also contain amphetamine at a concentration equal to or greater than 100 ng/mL.

TABLE 4 TO PARAGRAPH (b)(1)—ORAL FLUID, CONFIRMATORY TEST CUTOFF LEVELS FOR DRUGS AND DRUG METABOLITES

Drugs or drug metabolites	Cutoff level [nanograms (ng)/mL]
Marijuana (THC)	2
Cocaine	8
Benzoyllecgonine	8
Opioids:	
Codeine	15
Morphine	15
Hydrocodone	15
Hydromorphone	15
Oxycodone	15
Oxymorphone	15
6-acetylmorphine (6-AM)	2
Phencyclidine (PCP)	10
Amphetamines:	
Amphetamine	25
Methamphetamine	25
Methylenedioxymethamphetamine (MDMA)	25
Methylenedioxyamphetamine (MDA)	25

* * * * *

■ 28. In § 26.165:

■ a. Add a fifth sentence to paragraph (b)(2); and

■ b. Revise paragraph (b)(3);

■ c. In paragraph (f)(1) introductory text, remove the phrase “If the results of testing Bottle B or retesting the aliquot of a single specimen are negative, the licensee or other entity—” and add in its place the phrase “If the results of testing Bottle B or retesting the aliquot of a single specimen are negative, the MRO shall report a cancelled test result to the licensee or other entity, and the licensee and other entity—”; and

■ d. Revise paragraph (f)(2).

The addition and revisions read as follows:

§ 26.165 Testing split specimens and retesting single specimens.

* * * * *

(b) * * *

(2) * * * The MRO shall document in his or her records when (*i.e.*, date and time) the request was received from the donor to retest an aliquot of the single specimen or to test the Bottle B split specimen.

(3) No entity, other than the MRO as permitted in § 26.185(l), may order the retesting of an aliquot of the single specimen or the testing of the Bottle B split specimen.

* * * * *

(f) * * *

(2) If a donor requests that Bottle B be tested or that an aliquot of the single specimen be retested, and either Bottle B or the single specimen are not available due to circumstances outside of the donor's control (including, but not limited to, circumstances in which there is an insufficient quantity of the single specimen or the specimen in Bottle B to permit retesting, either Bottle B or the original single specimen is lost in transit to the second HHS-certified laboratory, or Bottle B has been lost at the HHS-certified laboratory or licensee testing facility), the MRO shall cancel the test, report a cancelled test result to the licensee or other entity for the donor's specimen, and inform the licensee or other entity that another collection is required under direct observation as soon as reasonably practical. The donor shall receive no notice of the collection requirement before he or she is instructed to proceed to the collection site. The licensee or other entity shall continue to administratively withdraw the individual's authorization, as required by § 26.165(f)(1) until the results of the second specimen collection have been received by the MRO. The licensee or other entity shall eliminate from the donor's personnel and other records any matter that could link the donor to the original positive, adulterated, or substituted test result(s) and any temporary administrative action, and may not impose any sanctions on the donor for a cancelled test. If test results from the second specimen collected are positive, adulterated, or substituted and the MRO determines that the donor has violated the FFD policy, the licensee or other entity shall impose the appropriate sanctions specified in subpart D of this part, but may not consider the original confirmed positive, adulterated, or substituted test result that was reported as a cancelled

test by the MRO under § 26.129(b)(2) or § 26.159(b)(2) in determining the appropriate sanctions.

■ 29. In § 26.167:

■ a. In the paragraph (c) heading, remove the phrase “validity tests” and add in its place the phrase “validity tests on urine”;

■ b. In paragraph (d)(1), remove the phrase “Any initial drug test performed by an HHS-certified laboratory” and add in its place the phrase “Any initial drug test of urine performed by an HHS-certified laboratory”;

■ c. Republish paragraph (d)(3) introductory text, and revise paragraphs (d)(3)(i) through (iii);

■ d. Revise paragraph (d)(4);

■ e. Revise paragraph (e)(2), republish paragraph (e)(3) introductory text, and revise paragraphs (e)(3)(i) through (iv); and

■ f. In paragraph (f)(3), in the third sentence, remove the words “responsible person” and add in their place the words “Responsible Person”.

The republications and revisions read as follows:

§ 26.167 Quality assurance and quality control.

* * * * *

(d) * * *

(3) Quality control samples for each analytical run of specimens for initial testing must include—

(i) At least one control certified to contain no drug or drug metabolite;

(ii) At least one positive control with the drug or drug metabolite targeted at 25 percent above the cutoff;

(iii) At least one positive control with the drug or drug metabolite targeted at 75 percent of the cutoff;

* * * * *

(4) A minimum of 10 percent of the total specimens in each analytical run must be quality control samples (*i.e.*, calibrators and controls), as defined by paragraphs (d)(3)(i) through (iv) of this section.

(e) * * *

(2) A minimum of 10 percent of the total specimens in each analytical run must be quality control samples (*i.e.*, calibrators and controls).

(3) Each analytical run of specimens that are subjected to confirmatory testing must include—

(i) At least one control certified to contain no drug or drug metabolite;

(ii) A calibrator with its drug concentration at the cutoff;

(iii) At least one positive control with the drug or drug metabolite targeted at 25 percent above the cutoff; and

(iv) At least one control targeted at or below 40 percent of the cutoff.

* * * * *

■ 30. In § 26.168, revise paragraph (h)(1) to read as follows:

§ 26.168 Blind performance testing.

* * * * *

(h) * * *

(1) Ensure that all blind performance test sample lots are placed in service by the supplier only after confirmation by an HHS-certified laboratory;

* * * * *

■ 31. In § 26.169:

■ a. In paragraph (a), remove the words “certifying scientist” and add in their place the words “Certifying Scientist”;

■ b. In paragraph (c)(2), remove the word “opiate”;

■ c. In paragraph (h) introductory text, in the first sentence, remove the word “urinalysis”;

■ d. Republish paragraph (h)(3) introductory text and revise paragraphs (h)(3)(i) and (ii), (h)(3)(iii) introductory text, and (h)(3)(iii)(B) and (C);

■ e. Add paragraphs (h)(3)(iii)(D) through (G);

■ f. Revise paragraph (h)(3)(iv);

■ g. Republish paragraph (h)(3)(v) introductory text and revise paragraph (h)(3)(v)(A); and

■ h. Add paragraphs (h)(3)(v)(C) and (D).

The republications, revisions, and additions read as follows:

§ 26.169 Reporting results.

* * * * *

(h) * * *

(3) Number of specimens reported as positive on confirmatory tests by drug or drug metabolite for which testing is conducted, including, but not limited to—

(i) Marijuana metabolite (as THCA);

(ii) Cocaine metabolite (as benzoylecgonine);

(iii) Opioids (total);

* * * * *

(B) Morphine;

(C) 6-acetylmorphine (6-AM);

(D) Hydrocodone;

(E) Hydromorphone;

(F) Oxycodone; and

(G) Oxymorphone;

(iv) Phencyclidine (PCP);

(v) Amphetamines (total);

(A) Amphetamine;

* * * * *

(C)

Methylenedioxymethamphetamine (MDMA); and

(D) Methylenedioxyamphetamine (MDA);

* * * * *

■ 32. In § 26.183, revise paragraphs (c) introductory text, (c)(1), and (d)(2)(ii) to read as follows:

§ 26.183 Medical review officer.

* * * * *

(c) *Responsibilities*. The primary role of the MRO is to review and interpret positive, adulterated, substituted, invalid, and dilute test results obtained through the licensee’s or other entity’s testing program and to identify any evidence of subversion of the testing process. The MRO is also responsible for identifying any issues associated with collecting and testing specimens, and for advising and assisting FFD program management in planning and overseeing the overall FFD program.

(1) In carrying out these responsibilities, the MRO shall examine alternate medical explanations for any positive, adulterated, substituted, invalid, or dilute test result. This action may include, but is not limited to, conducting a medical interview with the donor, reviewing the donor’s medical history, or reviewing any other relevant biomedical factors. The MRO shall review all medical records that the donor may make available when a positive, adulterated, substituted, invalid, or dilute test result could have resulted from responsible use of legally prescribed medication, a documented condition or disease state, or the demonstrated physiology of the donor.

* * * * *

(d) * * *

(2) * * *

(ii) The staff reviews of positive, adulterated, substituted, invalid, and dilute test results must be limited to reviewing the Federal CCF to determine whether it contains any errors that may require corrective action and to ensure that it is consistent with the information on the MRO’s copy. The staff may resolve errors in Federal CCFs that require corrective action(s), but shall forward the Federal CCFs to the MRO for review and approval of the resolution.

* * * * *

■ 33. In § 26.185:

■ a. Redesignate paragraph (f)(3) as paragraph (f)(4) and add new paragraph (f)(3);

■ b. In paragraph (g)(1), remove the reference “paragraph (g)(4)” and add in its place the reference “paragraph (g)(3)”;

■ c. Revise paragraphs (g)(2) introductory text and (g)(2)(iii);

■ d. Remove paragraph (g)(3), and redesignate paragraphs (g)(4) and (5) as paragraphs (g)(3) and (4), respectively;

■ e. In newly redesignated paragraph (g)(3), remove the phrase “any opium, opiate, or opium derivative (*e.g.*, morphine/codeine)” and add in its place “opioids (*i.e.*, morphine and/or codeine)”;

■ f. Revise the paragraph (j) heading and the first sentence in paragraph (j)(1); and

■ g. In paragraph (j)(2), remove the word “opiates” and add in its place the word “opioids”; in paragraph (j)(3), remove the word “opiates” and add in its place the phrase “opioids (*i.e.*, morphine and/or codeine)”; and in paragraph (j)(4) introductory text, remove the word “opiates” and add in its place the word “opioids”.

The addition and revisions read as follows:

§ 26.185 Determining a fitness-for-duty policy violation.

* * * * *

(f) * * *

(3) If the MRO and the laboratory agree that further testing would not be useful and there is no legitimate technical or medical explanation, and the invalid result is based on pH in the range of 9.0 to 9.5, the MRO shall consider whether there is evidence of elapsed time, exposure of the specimen to high temperature, or both that could account for the pH value. If an acceptable explanation exists for the invalid test result due to pH, based on objective and sufficient information, that elapsed time, high temperature, or both caused the high pH and donor action did not result in the invalid pH result, the MRO shall report a cancelled test result to the licensee or other entity, cancel the test result, and direct the licensee or other entity to collect a second urine specimen from the donor as soon as reasonably practicable. The second specimen collected may not be collected under direct observation.

* * * * *

(g) * * *

(2) If the results of the special analysis testing required by § 26.163(a)(2) are positive, the MRO determines that there is no legitimate medical explanation for the presence of the drug(s) or drug metabolite(s) in the specimen, and a clinical examination, if required under

paragraph (g)(3) of this section, has been conducted under paragraph (j) of this section, the MRO shall determine whether the positive and dilute specimen is a refusal to test. If the MRO does not have sufficient reason to believe that the positive and dilute specimen is a subversion attempt, he or she shall determine that the drug test results are positive and that the donor has violated the FFD policy. When determining whether the donor has diluted the specimen in a subversion attempt, the MRO shall also consider the following circumstances, if applicable:

* * * * *

(iii) The collector observed conduct indicating an attempt to dilute the specimen.

* * * * *

(j) *Review for opioids and prescription and over-the-counter medications.* (1) If the MRO determines that there is no legitimate medical explanation for a positive confirmatory test result for opioids (*i.e.*, morphine and/or codeine) and before the MRO determines that the test result is a violation of the FFD policy, the MRO or his/her designee, who shall also be a licensed physician with knowledge of the clinical signs of drug abuse, shall determine that there is clinical evidence, in addition to the positive confirmatory test result, that the donor has illegally used morphine and/or codeine. * * *

* * * * *

■ 34. In § 26.405, revise paragraph (d) to read as follows:

§ 26.405 Drug and alcohol testing.

* * * * *

(d) At a minimum, licensees and other entities shall test specimens for marijuana metabolite, cocaine metabolite, opioids (codeine, morphine, 6-acetylmorphine, hydrocodone, hydromorphone, oxycodone, and

oxymorphone), amphetamines (amphetamine, methamphetamine, methylenedioxymethamphetamine, and methylenedioxyamphetamine), phencyclidine, and alcohol at the cutoff levels specified in this part, or comparable cutoff levels if specimens other than urine are collected for drug testing. Urine specimens collected for drug testing must be subject to validity testing that includes testing for adulterants.

* * * * *

§ 26.415 [Amended]

■ 35. In § 26.415, in paragraph (c), remove the citation “(65 FR 41944; August 9, 2001)”.

§ 26.715 [Amended]

■ 36. In § 26.715, in paragraph (b)(1), remove the phrase “collection site, licensee testing facility, or HHS-certified laboratory” and add in its place the phrase “collection site or licensee testing facility.”

■ 37.

■ 38. In § 26.717, revise paragraphs (b)(3) and (4) to read as follows:

§ 26.717 Fitness-for-duty program performance data.

* * * * *

(b) * * *

(3) Populations tested (*i.e.*, licensee or other entity employees, C/Vs);

(4) Number of tests administered and results of those tests sorted by population tested (*i.e.*, licensee or other entity employees, C/Vs);

* * * * *

Dated November 9, 2022.

For the Nuclear Regulatory Commission.

Brooke P. Clark,

Secretary of the Commission.

[FR Doc. 2022-24903 Filed 11-21-22; 8:45 am]

BILLING CODE 7590-01-P



FEDERAL REGISTER

Vol. 87

Tuesday,

No. 224

November 22, 2022

Part III

Department of the Interior

Fish and Wildlife Service
50 CFR Part 17

Endangered and Threatened Wildlife and Plants; Designation of Critical
Habitat for Endangered Florida Bonneted Bat; Proposed Rule

DEPARTMENT OF THE INTERIOR**Fish and Wildlife Service****50 CFR Part 17**

[Docket No. FWS-R4-ES-2019-0106;
FF09E21000 FXES1111090FEDR 234]

RIN 1018-BE10

**Endangered and Threatened Wildlife
and Plants; Designation of Critical
Habitat for Endangered Florida
Bonneted Bat**

AGENCY: Fish and Wildlife Service,
Interior.

ACTION: Revised proposed rule; request
for comments.

SUMMARY: We, the U.S. Fish and Wildlife Service (Service), are revising our proposed designation of critical habitat for the Florida bonneted bat (*Eumops floridanus*) under the Endangered Species Act of 1973 (Act), as amended. In response to new information we received and public comments on our June 10, 2020, proposed rule, we are now proposing to designate approximately 1,174,011 acres (475,105 hectares) in 13 Florida counties as critical habitat for the species. We also announce the availability of a draft economic analysis (DEA) of the revised proposed designation of critical habitat for the Florida bonneted bat. We request comments from all interested parties on this revised proposed rule and the associated DEA. Comments submitted on our June 10, 2020, proposed rule need not be resubmitted as they will be fully considered in the preparation of the final rule. If we finalize this rule as proposed, it would extend the Act's protections to this species' critical habitat.

DATES: We will accept comments on this revised proposed rule and the DEA that are received or postmarked on or before January 23, 2023. Comments submitted electronically using the Federal eRulemaking Portal (see **ADDRESSES**, below) must be received by 11:59 p.m. Eastern Time on the closing date. We must receive requests for a public hearing, in writing, at the address shown in **FOR FURTHER INFORMATION CONTACT** by January 6, 2023.

ADDRESSES: *Written comments:* You may submit comments by one of the following methods:

(1) *Electronically:* Go to the Federal eRulemaking Portal: <https://www.regulations.gov>. In the Search box, enter FWS-R4-ES-2019-0106, which is the docket number for this rulemaking. Then, click on the Search button. On the

resulting page, in the Search panel on the left side of the screen, under the Document Type heading, check the Proposed Rule box to locate this document. You may submit a comment by clicking on "Comment."

(2) *By hard copy:* Submit by U.S. mail to: Public Comments Processing, Attn: FWS-R4-ES-2019-0106, U.S. Fish and Wildlife Service, MS: PRB/3W, 5275 Leesburg Pike, Falls Church, VA 22041-3803.

We request that you send comments only by the methods described above. We will post all comments on <https://www.regulations.gov>. This generally means that we will post any personal information you provide us (see Information Requested, below, for more information).

Availability of supporting materials: The DEA and other supporting documents are included in the decision file and are available at <https://www.regulations.gov> under Docket No. FWS-R4-ES-2019-0106. Coordinates or plot points or both from which the critical habitat maps are generated are available at <https://www.regulations.gov> under Docket No. FWS-R4-ES-2019-0106 and the Florida Ecological Services Field Office website at <https://www.fws.gov/office/florida-ecological-services/library>.

FOR FURTHER INFORMATION CONTACT:

Lourdes Mena, Classification and Recovery Division Manager, U.S. Fish and Wildlife Service, Florida Ecological Services Field Office, 7915 Baymeadows Way, Suite 200, Jacksonville, FL 32256; telephone (904) 731-3134. Individuals in the United States who are deaf, deafblind, hard of hearing, or have a speech disability may dial 711 (TTY, TDD, or TeleBraille) to access telecommunications relay services. Individuals outside the United States should use the relay services offered within their country to make international calls to the point-of-contact in the United States.

SUPPLEMENTARY INFORMATION:

Executive Summary

Why we need to publish a rule. Under the Endangered Species Act, when we determine that any species is an endangered or threatened species, we are required to designate critical habitat, to the maximum extent prudent and determinable. Designations of critical habitat can only be completed by issuing a rule.

What this document does. This document revises the proposed designation of critical habitat for the Florida bonneted bat to include a total of approximately 1,174,011 acres

(475,105 hectares) in portions of 13 Florida counties. On October 2, 2013, we published in the **Federal Register** (78 FR 61004) a final rule listing the Florida bonneted bat as an endangered species. On June 10, 2020, we published in the **Federal Register** (85 FR 35510) a proposed rule to designate critical habitat for this species. This document revises the proposed designation of critical habitat for the Florida bonneted bat.

The basis for our action. Section 3(5)(A) of the Act defines critical habitat as (i) the specific areas within the geographical area occupied by the species, at the time it is listed, on which are found those physical or biological features (I) essential to the conservation of the species and (II) which may require special management considerations or protections; and (ii) specific areas outside the geographical area occupied by the species at the time it is listed, upon a determination by the Secretary that such areas are essential for the conservation of the species. Section 4(b)(2) of the Act states that the Secretary must make the designation on the basis of the best scientific data available and after taking into consideration the economic impact, the impact on national security, and any other relevant impacts of specifying any particular area as critical habitat.

Draft economic analysis of the revised proposed designation of critical habitat. In order to consider the economic impacts of critical habitat for the Florida bonneted bat, we compiled information pertaining to the potential incremental economic impacts for this revised proposed critical habitat designation. The information we used in determining the economic impacts of the revised proposed critical habitat is summarized in this revised proposed rule (see *Consideration of Economic Impacts*, below) and is available at <https://www.regulations.gov> at Docket No. FWS-R4-ES-2019-0106. We are soliciting public comments on the economic information provided and any other potential economic impacts of this revised proposed designation. We will continue to reevaluate the potential economic impacts between this proposal and our final designation.

Public comment. We requested and received public comments on our June 10, 2020, proposed rule to designate critical habitat for the Florida bonneted bat. Those comments primarily consist of requests for exclusion, requests for the designation of additional areas, and comments on the physical or biological features and associated methodology used to identify proposed units (see New Information and Revisions to

Previously Proposed Critical Habitat, below). Those comments are already part of the public record of this rulemaking proceeding and are available for public viewing at <https://www.regulations.gov> under Docket No. FWS-R4-ES-2019-0106. We now seek comments and solicit information from the public on this revised proposed designation to make sure we consider the best scientific and commercial information available in developing our final designation. Because we will consider all comments and information we receive during the comment period, our final determination may differ from this proposal. We will provide responses to comments we received during both public comment periods in our final rule.

Peer review. We sought peer review on our June 10, 2020, proposed rule and received comments from two reviewers (see New Information and Revisions to Previously Proposed Critical Habitat, below). We are again seeking comments from independent specialists to ensure that this revised proposed designation of critical habitat for the Florida bonneted bat is based on scientifically sound data and analyses. We have invited these peer reviewers to comment on our specific assumptions and conclusions in this revised critical habitat proposal.

Information Requested

We intend that any final action resulting from this revised proposed rule will be based on the best scientific and commercial data available and be as accurate and as effective as possible. Therefore, we request comments or information from other governmental agencies, Native American Tribes, the scientific community, industry, or any other interested parties concerning this revised proposed rule. Please note that comments submitted on our June 10, 2020, proposed rule need not be resubmitted as they will be fully considered in the preparation of the final rule. Additionally, due to the ongoing challenges regarding the 2019 regulations, we also seek comments on whether and how applying the regulations that were in effect before the 2019 regulations would alter any of these analyses.

We particularly seek comments concerning:

(1) The reasons why we should or should not designate habitat as “critical habitat” under section 4 of the Act (16 U.S.C. 1531 *et seq.*), including information to inform the following factors that the regulations identify as reasons why designation of critical habitat may be not prudent:

(a) The species is threatened by taking or other human activity and identification of critical habitat can be expected to increase the degree of such threat to the species;

(b) The present or threatened destruction, modification, or curtailment of a species’ habitat or range is not a threat to the species, or threats to the species’ habitat stem solely from causes that cannot be addressed through management actions resulting from consultations under section 7(a)(2) of the Act;

(c) Areas within the jurisdiction of the United States provide no more than negligible conservation value, if any, for a species occurring primarily outside the jurisdiction of the United States; or

(d) No areas meet the definition of critical habitat.

(e) The Secretary otherwise determines that designation of critical habitat would not be prudent based on the best scientific data available.

In addition, we seek comment regarding whether and how this information would differ under the factors that the pre-2019 regulations identify as reasons why designation of critical habitat may be prudent.

(2) Specific information on:

(a) The amount and distribution of Florida bonneted bat habitat;

(b) Any additional areas occurring within the range of the species (*i.e.*, Miami-Dade, Monroe, Lee, Collier, Charlotte, Polk, Osceola, Okeechobee, Highlands, Broward, Sarasota, Hardee, Glades, Palm Beach, Martin, and DeSoto Counties, Florida) that should be included in the designation because they (i) were occupied at the time of listing and contain the physical or biological features that are essential to the conservation of the species and that may require special management considerations, or (ii) were unoccupied at the time of listing and are essential for the conservation of the species.

(c) Special management considerations or protection that may be needed in critical habitat areas we are proposing, including information related to the impacts that noise and light pollution and pesticides usage may have on critical habitat, as well as managing for the potential effects of climate change; and

(d) For areas not occupied at the time of listing essential for the conservation of the species, we particularly seek comments:

(i) Regarding whether occupied areas are adequate for the conservation of the species; and

(ii) Providing specific information regarding whether or not unoccupied areas would, with reasonable certainty,

contribute to the conservation of the species and contain at least one physical or biological feature essential to the conservation of the species.

We also seek comments or information regarding whether areas not occupied at the time of listing could be considered habitat for the species.

(3) Characteristics of roost trees.

(4) Land use designations and current or planned activities in the subject areas and their possible impacts on proposed critical habitat.

(5) Any probable economic, national security, or other relevant impacts of designating any area that may be included in the final designation, and the related benefits of including or excluding specific areas.

(6) Information on the extent to which the description of probable economic impacts in the draft economic analysis (DEA) for the revised proposed rule is a reasonable estimate of the likely economic impacts and any additional information regarding probable economic impacts that we should consider.

(7) Whether any specific areas we are proposing for critical habitat designation should be considered for exclusion under section 4(b)(2) of the Act, and whether the benefits of potentially excluding any specific area outweigh the benefits of including that area under section 4(b)(2) of the Act. We are particularly interested in information concerning those areas described below in tables 2 and 3. If you think we should exclude these or any additional areas, please provide information regarding the benefit of exclusion that you have not already submitted to us, as comments submitted on our June 10, 2020, proposed rule need not be resubmitted and will be fully considered in the preparation of the final rule.

(8) Whether we could improve or modify our approach to designating critical habitat in any way to provide for greater public participation and understanding, or to better accommodate public concerns and comments.

Please include sufficient information with your submission (such as scientific journal articles or other publications) to allow us to verify any scientific or commercial information you include.

Please note that submissions merely stating support for, or opposition to, the action under consideration without providing supporting information, although noted, will not be considered in making a final critical habitat determination.

You may submit your comments and materials concerning this proposed rule

by one of the methods listed in **ADDRESSES**. We request that you send comments only by the methods described in **ADDRESSES**.

If you submit information via <https://www.regulations.gov>, your entire submission—including any personal identifying information—will be posted on the website. If your submission is made via a hardcopy that includes personal identifying information, you may request at the top of your document that we withhold this information from public review. However, we cannot guarantee that we will be able to do so. We will post all hardcopy submissions on <https://www.regulations.gov>.

Comments and materials we receive, as well as supporting documentation we used in preparing this proposed rule, will be available for public inspection at <https://www.regulations.gov> under Docket No. FWS-R4-ES-2019-0106.

Because we will consider all comments and information we receive during the comment period, our final determination may differ from this revised proposal. Based on the new information we receive (and any comments on that new information), our final designation may not include all areas proposed, may include some additional areas that meet the definition of critical habitat, and may exclude some areas if we find the benefits of exclusion outweigh the benefits of inclusion.

Public Hearing

Section 4(b)(5) of the Act provides for a public hearing on this proposal, if requested. Requests must be received by the date specified in **DATES**. Such requests must be sent to the address shown in **FOR FURTHER INFORMATION CONTACT**. We will schedule a public hearing on this proposal, if requested, and announce the date, time, and place of the hearing, as well as how to obtain reasonable accommodations, in the **Federal Register** and local newspapers at least 15 days before the hearing. We may hold the public hearing in person or virtually via webinar. We will announce any public hearing on our website, in addition to the **Federal Register**. The use of these virtual public hearings is consistent with our regulations at 50 CFR 424.16(c)(3).

Previous Federal Actions

Federal actions for the Florida bonneted bat that occurred prior to October 4, 2012, are outlined in our proposed listing rule for the species (see 77 FR 60750, October 4, 2012). On October 2, 2013, after consideration of the available scientific information, and peer review and public comments on

the proposed listing rule, we listed the Florida bonneted bat as an endangered species (78 FR 61004). Critical habitat was considered prudent but not determinable at the time of listing due to the lack of information on the physical or biological features essential for the species' conservation. Additional research helped define those physical or biological features, and on June 10, 2020, we proposed to designate critical habitat for the Florida bonneted bat (85 FR 35510). During the public comment period on the June 10, 2020, proposed rule, we received significant new information on genetics as well as presence and roost data; following the comment period, we developed a conservation strategy to serve as a foundation for critical habitat criteria and methodology, revised the physical or biological features essential for the conservation of the species, and revised our proposed critical habitat designation in lieu of preparing a final rule. This document presents our revised proposed critical habitat designation for the Florida bonneted bat.

Supporting Documents

Starting in 2016, the Service has been preparing species status assessment (SSA) reports to compile and evaluate the best scientific information available to inform listing and other decisions under the Act. Since this species was listed before this process was implemented, there was no SSA for the Florida bonneted bat at the time the proposed critical habitat designation published (June 10, 2020). A recovery outline and a conservation strategy have been prepared for this species. The Florida Bonneted Bat Recovery Outline is a brief document that broadly sketches the interim conservation and management program for the Florida bonneted bat during the time between the final listing under the Act and completion of a recovery plan. The Florida Bonneted Bat Conservation Strategy provides a technical foundation for recovery strategies, summarizing the best scientific data available concerning the status of the species and threats affecting the species, and outlines goals and objectives for achieving recovery of the Florida bonneted bat. These documents have been prepared based on input and information from researchers and species experts.

Additional documents that we considered in revising our proposed critical habitat designation include a list of conservation lands that overlap with the proposed designation, conservation and natural resource management plans for areas we are considering for exclusion, and a summary of the habitat

analysis conducted to inform delineation of the proposed critical habitat units. All of these supporting documents are available at <https://www.regulations.gov> under Docket No. FW-R4-ES-2019-0106.

Background

The purpose of this document is to discuss only those topics directly relevant to this revised proposed critical habitat designation. For more information on the species, its habitat, and previous Federal actions concerning the Florida bonneted bat, refer to the final listing rule published in the **Federal Register** on October 2, 2013 (78 FR 61004) and the proposed critical habitat rule published in the **Federal Register** on June 10, 2020 (85 FR 35510).

In 2019, jointly with the National Marine Fisheries Service, the Service issued final rules that revised the regulations in 50 CFR parts 17 and 424 regarding how we add, remove, and reclassify threatened and endangered species and the criteria for designating listed species' critical habitat (84 FR 45020 and 84 FR 44752; August 27, 2019; collectively, the 2019 regulations). However, on July 5, 2022, the U.S. District Court for the Northern District of California vacated the 2019 regulations (*Center for Biological Diversity v. Haaland*, No. 4:19-cv-05206-JST, Doc. 168 (N.D. Cal. July 5, 2022) (*CBD v. Haaland*)), reinstating the regulations that were in effect before the effective date of the 2019 regulations as the law governing species classification and critical habitat decisions. Subsequently, on September 21, 2022, the U.S. Circuit Court of Appeals for the Ninth Circuit stayed the district court's July 5, 2022, order vacating the 2019 regulations until a pending motion for reconsideration before the district court is resolved (In re: Cattlemen's Ass'n, No. 22-70194). The effect of the stay is that the 2019 regulations are the governing law as of September 21, 2022.

Due to the continued uncertainty resulting from the ongoing litigation, we also undertook an analysis of whether the proposal would be different if we were to apply the pre-2019 regulations. That analysis, which we described in a separate memo in the decisional file and posted on <https://www.regulations.gov>, concluded that we would have reached the same proposal if we had applied the pre-2019 regulations because under either regulatory scheme we find that critical habitat is prudent and that the occupied areas proposed for the Florida bonneted bat are adequate to ensure the conservation of the species.

In our June 10, 2020, proposed rule, we proposed to designate critical habitat

in four units encompassing approximately 1,478,333 acres (ac) (598,261 hectares (ha)) in portions of 10 Florida counties. In addition, we announced the availability of a DEA of the proposed critical habitat designation. We accepted comments on the proposed critical habitat designation and DEA for 60 days, ending August 10, 2020. Based on information we received during the public comment period, we are revising our proposed critical habitat designation for the Florida bonneted bat. This revised proposed rule has a 60-day comment period (see **DATES**, above) to allow all interested parties to submit comments on our revised proposed critical habitat designation for the Florida bonneted bat.

New Information and Revisions to Previously Proposed Critical Habitat

During the public comment period on our June 10, 2020, proposed rule, we received over 1,800 responses, as well as comments from two peer reviewers. We received comments questioning the essential physical or biological features we identified (specifically, our description of representative forest types, definition and use of “core areas,” and definition and use of a minimum patch size) and the relationship of those features to our critical habitat criteria and methodology. Because our incorporation of a minimum patch size precluded the consideration of habitat within urban Miami-Dade County, many comments addressed the importance of this area to the species and provided information (e.g., historical use, observed activity) regarding why it meets the definition of critical habitat. Comments received also addressed the need to directly incorporate all available presence information into our habitat analysis and critical habitat methodology and expressed concerns regarding a lack of redundancy provided in the proposed units for the species to withstand catastrophic events. In addition, since the proposed rule was published, we received new information regarding genetic diversity and structure of the species, as well as new presence and roost data. Upon further review of the best available information, we have decided to use average measurements to describe the characteristics of roost trees rather than the minimum measurements used in our June 10, 2020, proposed rule. In this revision, we also provide additional roost-related measurements to better reflect the characteristics required by the Florida bonneted bat.

Therefore, after fully considering the public comments we received on our June 10, 2020, proposed rule and new

information that became available after the publication of that proposed rule, we revise our proposed critical habitat designation for the Florida bonneted bat based on changes to the physical or biological features and the criteria and methodology used to identify those specific areas that constitute critical habitat. Due to the comprehensive nature of these revisions, this document presents an entirely new, revised proposed critical habitat designation for the species. The DEA for the proposed critical habitat designation has also been revised and is summarized below (see *Consideration of Economic Impacts*).

Physical or Biological Features Essential to the Conservation of the Species

In accordance with section 3(5)(A)(i) of the Act and regulations at 50 CFR 424.12(b), in determining which areas we will designate as critical habitat from within the geographical area occupied by the species at the time of listing, we consider the physical or biological features that are essential to the conservation of the species and that may require special management considerations or protection. The regulations at 50 CFR 424.02 define “physical or biological features essential to the conservation of the species” as the features that occur in specific areas and that are essential to support the life-history needs of the species, including, but not limited to, water characteristics, soil type, geological features, sites, prey, vegetation, symbiotic species, or other features. A feature may be a single habitat characteristic or a more complex combination of habitat characteristics. Features may include habitat characteristics that support ephemeral or dynamic habitat conditions. Features may also be expressed in terms relating to principles of conservation biology, such as patch size, distribution distances, and connectivity. For example, physical features essential to the conservation of the species might include gravel of a particular size required for spawning, alkaline soil for seed germination, protective cover for migration, or susceptibility to flooding or fire that maintains necessary early-successional habitat characteristics. Biological features might include prey species, forage grasses, specific kinds or ages of trees for roosting or nesting, symbiotic fungi, or a particular level of nonnative species consistent with conservation needs of the listed species. The features may also be combinations of habitat characteristics and may encompass the relationship between characteristics or the necessary amount

of a characteristic essential to support the life history of the species.

In considering whether features are essential to the conservation of the species, we may consider an appropriate quality, quantity, and spatial and temporal arrangement of habitat characteristics in the context of the life-history needs, condition, and status of the species. These characteristics include, but are not limited to, space for individual and population growth and for normal behavior; cover or shelter; sites for breeding, reproduction, or rearing (or development) of offspring; food, water, air, light, minerals, or other nutritional or physiological requirements; and habitats with appropriate disturbance regimes (for more information, see the proposed listing rule (77 FR 60750; October 4, 2012) and the Florida Bonneted Bat Conservation Strategy (see Supporting Documents)). We summarize below the more important habitat characteristics, particularly those that support the description of physical and biological features essential to the conservation of the Florida bonneted bat. For *Food, Water, Air, Light, Minerals, or Other Nutritional or Physiological Requirements*, please see this section in the proposed critical habitat rule (85 FR 35510, June 10, 2020). We also consider these habitat features relative to the scale at which Florida bonneted bats use the features, allowing us to more logically organize the physical and biological features to delineate the critical habitat.

Space for Individual and Population Growth and for Normal Behavior

Due to the spatial variability of their prey, large size, and wing morphology, this species has significant spatial needs for foraging. Insect abundance, density, and community composition frequently vary across space and over time based on season and environmental conditions. As a result of this spatial variability, Florida bonneted bats may need to travel far distances and feed over large areas to satisfy dietary needs. For example, Florida bonneted bats from Fred C. Babcock-Cecil M. Webb Wildlife Management Area (Babcock-Webb WMA), on average, traveled 9.5 miles (mi) (15 kilometers (km)) from their roosts and flew 24 mi (39 km) total per night (Webb et al. 2018, p. 8; Webb 2018, pers. comm.). These bats also traveled maximum distances of over 24 mi (39 km) from their roosts and over 56 mi (90 km) total in one night (Webb et al. 2018, p. 8; Webb 2018, pers. comm.). Florida bonneted bats also require open areas for foraging due to their large body size and morphology of

their wings, which are designed for fast and efficient, but less maneuverable, flight.

This large bat relies on swarms of larger insects for feeding; thus, foraging habitat for the Florida bonneted bat consists of areas that hatch and concentrate insects of this size, including vegetated areas and waterways. These bats also frequently feed on insects from agricultural areas and golf courses (Bailey et al. 2017a, entire).

Ecologically diverse areas of suitable habitat representing the geographic extent of the species' range are also important for population growth and persistence. The major ecological communities (Myers and Ewel 1990, entire; Service 1999, entire; FNAI 2010, entire) that provide Florida bonneted bat roosting habitat in central and southern Florida include: pine rocklands (south Florida rockland, rockland pine forest, rockland hammock); cypress communities (cypress swamps, strand swamps, domes, sloughs, ponds); hydric pine flatwoods (wet flatwoods); mesic pine flatwoods; and high pine. A variety of other habitats may be used as well (Bailey et al. 2017a, entire). Diverse, open foraging habitats (e.g., prairies, riverine habitat) are also important. Adequate roosting and foraging habitats are essential to the species, as they provide the diversity necessary to allow for population resiliency following minor disturbances (e.g., loss of roost tree, cold snap) as well as more significant stochastic events (e.g., hurricane, drought, forest disease, climate change).

Structural connectivity (suitable habitat in the form of linear corridors or patches creating "stepping stones") facilitates the recolonization of extirpated populations; facilitates the establishment of new populations; and allows for natural behaviors needed for foraging, exploratory movements, and dispersal. Four genetically differentiated populations of the Florida bonneted bat have been identified (Charlotte, Polk/Osceola, Lee/Collier, and Miami-Dade Counties) (Austin et al. 2022, entire; see also Florida Bonneted Bat Conservation Strategy in Supporting Documents). While dispersal of Florida bonneted bats appears to be geographically restricted between populations, the geographic extent of the four genetically differentiated areas is not yet known, and maintaining structural connectivity to allow for ongoing and future functional connectivity (i.e., actual movement of animals and/or exchange of genes) between known populations remains important to the species for

resiliency as well as population stability and growth (Austin et al. 2022, pp. 507–508). Structural connectivity in the form of vegetated corridors with opportunities for roosting and/or foraging, vegetated river corridors and other areas with freshwater available year-round, and habitat patches such as pine rockland fragments and tree islands are needed to provide and maintain connections between regions where known Florida bonneted bat populations occur. Maintaining viable populations in each of the known genetically differentiated areas and protecting connectivity is necessary for the demographic and genetic health of the species. Therefore, it is important that this species has areas of ecologically diverse and connected habitat including sufficient amounts of open foraging habitat.

Cover or Shelter

The Florida bonneted bat primarily roosts in tree cavities, either as individuals or small or large colonies (Ober et al. 2017, p. 378; Braun de Torrez et al. 2020a, p. 6; 2020b, entire). Roosts provide protection from sunlight, adverse weather, and predators; sites for mating, rearing of young, social interaction and information sharing, resting, and digestion of food; and microclimate stability (Kunz 1982, entire; Ormsbee et al. 2007, pp. 130–135; Marks and Marks 2008a, p. 4; Dechmann et al. 2010, pp. 1–7; Bohn 2012, in litt.).

Florida bonneted bat roosts are difficult to locate; only 36 natural roosts have been identified (not all currently occupied), the first in 2013 (Angell and Thompson 2015, entire; Braun de Torrez et al. 2020b, entire; Braun de Torrez 2021, pers. comm.; Borkholder 2022, pers. comm.; Braun de Torrez 2022, pers. comm.). Known natural roosts have been documented in the following tree species: slash pine (*Pinus elliottii*), longleaf pine (*Pinus palustris*), bald cypress (*Taxodium distichum*), and royal palm (*Roystonea regia*) (Braun de Torrez et al. 2020b, entire). A significant proportion of known roosts are in snags of these tree species (Braun de Torrez et al. 2020b, entire). One non-volant (flightless) pup was found at the base of a live oak (*Quercus virginiana*) hours after a tree cavity was bisected (Ridgley 2020, pers. comm.); it is not known if this tree species is commonly used as a roost site or may be used particularly where suitable trees are sparse.

Upon further review of the best available information, we have modified the features relevant to roost trees to more accurately reflect the characteristics required by Florida

bonneted bat. Relative to surrounding trees, Florida bonneted bat roost trees tend to have greater overall height (averaging 57 feet (ft) (17 meters (m)), diameter (averaging 15-inch (in) (38-centimeter (cm)) diameter at breast height (dbh)), and canopy height relative to the adjacent canopy (averaging 16 ft (5 m) taller than surrounding trees) (Braun de Torrez et al. 2020b, entire; Braun de Torrez 2022, pers. comm.). The species also appears to require sufficient unobstructed space for emergence, with cavities averaging 35 ft (10.7 m) above the ground and roost trees averaging 14 ft (4 m) from the nearest tree (Braun de Torrez et al. 2020b, entire; Braun de Torrez 2022, pers. comm.), often in open or semi-open canopy and canopy gaps. Cavities may require a minimum of approximately 19 ft (5.7 m) of ground clearance (Braun de Torrez et al. 2020b, entire; Braun de Torrez 2022, pers. comm.); however, there are two instances of Florida bonneted bats using bat houses with approximately 13 ft (4 m) of ground clearance in Miami-Dade County (Ridgley 2021, unpublished data). Collectively, this indicates that this species prefers large trees with adequate space around the cavity for emergence. Solitary males may roost under loose bark, and loose or shaggy bark has been documented as a night roost (e.g., *Melaleuca*). However, Florida bonneted bats typically roost in cavities made by other species (notably woodpeckers) or by natural damage caused by fire, storms, or decay.

The Florida bonneted bat is suspected to have high roost-site fidelity. Some roosts are used for several years by Florida bonneted bat colonies, possibly decades (Myers 2013, pers. comm.; Scofield 2013a–b, pers. comm.; 2014a–b, pers. comm.; Bohn 2014, pers. comm.; Gore et al. 2015, p. 183; Angell and Thompson 2015, p. 186; Hosein 2016, pers. comm.; Webb 2017, pers. comm.; B. Myers 2018, pers. comm.; Aldredge 2019, pers. comm.). Conversely, natural roosts may frequently succumb to natural causes (i.e., hurricanes, wildfire), resulting in total loss or too much damage to allow for future roosting. At least 37 percent of the known natural roosts discovered since 2013 are now uninhabitable (due to decay, hurricanes, and other factors) (Braun de Torrez et al. 2020b, entire). Suitable roost sites are a critical resource, are an ongoing need of the species, and may be limiting population growth and distribution in certain situations. The loss of a roost site may represent a greater impact to this species

relative to some other bat species (Ober 2012, in litt.).

Florida bonneted bats also roost in artificial structures (e.g., homes with barrel-tile roofs, chimneys, barns, hangars, utility poles) and bat houses (Marks and Marks 2008b, p. 8; Morse 2008, entire; Trokey 2012a–b, pers. comm.; Gore et al. 2015, entire; see *Use of Artificial Structures (Bat Houses)* in the final listing rule (78 FR 61004, October 2, 2013, p. 61010)). Despite clear evidence of their use, artificial bat houses may not be ideal or a sufficient surrogate for natural roosts. Pup mortalities and other events (e.g., pups falling from roosts and unable to climb up metal poles or wood poles with predator guards) have raised questions about heat build-up, insulation, proper placement in the landscape, and bat house design (Crawford and O’Keefe 2021, entire). Therefore, natural roosts (i.e., live or dead trees and tree snags, especially longleaf pine, slash pine, bald cypress, and royal palm, on average 57 ft (17 m) in height and an average 15-in (38-cm) dbh that are emergent from the surrounding canopy (by an average 16 ft (5 m)) and have unobstructed space for emergence) are important habitat characteristics for this species.

Sites for Breeding, Reproduction, or Rearing (or Development) of Offspring

Sites supporting the Florida bonneted bats’ breeding activities appear to be required year-round (Timm and Genoways 2004, p. 859; Ober et al. 2017, p. 382; Bailey et al. 2017b, p. 556; see also *Life History* in the final listing rule (78 FR 61004, October 2, 2013, pp. 61005–61006) and *Food, Water, Air, Light, Minerals, or Other Nutritional or Physiological Requirements* in the proposed critical habitat rule (85 FR 35510, June 10, 2020)). Reproductively active adults have been observed during August, December, and April capture sessions, and non-volant pups (young not yet capable of flying) have been documented in roosts in every month other than February and March (Scofield 2014b, pers. comm.; Angell and Thompson 2015, p. 186; Ridgley 2015, pers. comm.; Ober et al. 2017, pp. 381, 383–384; Gore 2017, pers. comm.; J. Myers 2018, pers. comm.; 2020, pers. comm.). Based upon these data, flightless young bonneted bats and females with high energetic demands due to pregnancy and lactation may be vulnerable to disturbance for at least 10 months of the year. Most roosting bats are sensitive to human disturbance (Kunz 1982, p. 32), and maternity colonies may be especially intolerant of disturbance (Harvey et al. 1999, p. 13; see also *Inadvertent and Purposeful*

Impacts from Humans in the final listing rule (78 FR 61004, October 2, 2013, pp. 61033–61034)).

Florida bonneted bat colonies conform to a harem structure (one dominant male, several reproductively active females and their young; Ober et al. 2017, p. 382). This type of social organization, together with evidence of high roost-site fidelity, underscores the importance of roosts to this species for population maintenance, growth, and natural behaviors. Disturbance of a roost at any time can alter social dynamics and impact reproductive success (Ober et al. 2017, p. 382). Accordingly, areas where roosting and other natural behaviors can occur undisturbed are important in considering the conservation of the species.

Food, Water, Air, Light, Minerals, or Other Nutritional or Physiological Requirements

Our discussion of these habitat characteristics is unchanged from the proposed rule (85 FR 35510, June 10, 2020).

Habitats With Appropriate Disturbance Regimes

The Florida bonneted bat not only requires healthy and ecologically diverse habitat; the species also needs areas with an appropriate disturbance regime. The Florida bonneted bat’s entire range is within the fire-dependent and fire-adapted landscape of central and south Florida (Noss 2018, entire). The species uses fire-dependent vegetation communities for roosting (Belwood 1992, pp. 219–220; Angell and Thompson 2015, entire; Braun de Torrez et al. 2016, p. 240) and foraging (Bailey et al. 2017a, entire; Braun de Torrez et al. 2018a–c, entire). Florida bonneted bats appear to be attracted to recently burned areas (Braun de Torrez et al. 2018a, entire); it appears that Florida bonneted bats are fire-adapted and benefit from prescribed burn programs that closely mimic historical fire regimes. Fires during the historical fire season (i.e., early wet season, April through June) at a moderate frequency (more than 3 to 5 years) appear to optimize habitat for bats in both pine flatwoods and prairies (Braun de Torrez et al. 2018b, pp. 6–9). Fire may result in an increase of suitable roosts (i.e., create more snags and cavities), more open flight space, and increased prey availability (Boyles and Aubrey 2006, pp. 111–113; Armitage and Ober 2012, pp. 107–109; O’Keefe and Loeb 2017, p. 271; Braun de Torrez et al. 2018a, p. 1120; 2018b, pp. 8–9).

Fire also has the potential to harm bats through disturbance or destruction

of roost trees (Morrison and Raphael 1993, p. 328; Dickinson et al. 2010, pp. 2196–2200). Despite the risks that Florida bonneted bats may abandon roosts, or roosts and pups may be lost during fires, it is critical for fires to occur on the landscape to maintain suitable habitat; precautions can be taken to reduce risks appropriately (see *Inadvertent Impacts from Land Management Practices*, below). Therefore, based on the information in this discussion, we identify areas of diverse habitat types and ecological communities maintained via appropriate disturbance regimes as essential physical or biological features for this species.

Summary of Essential Physical or Biological Features

We derive the specific physical or biological features essential to the conservation of Florida bonneted bat from studies of the species’ habitat, ecology, and life history as described below and further in the Florida Bonneted Bat Conservation Strategy (see Supporting Documents) and the proposed and final listing rules (77 FR 60750, October 4, 2012; 78 FR 61004, October 2, 2013). We have determined that the following physical or biological features are essential to the conservation of the Florida bonneted bat:

(1) Habitats that provide for roosting and rearing of offspring. Such habitat provides structural features for rest, digestion of food, social interaction, mating, rearing of young, protection from sunlight and adverse weather conditions, and cover to reduce predation risks for adults and young, and is generally characterized by:

(a) Live or dead trees and tree snags, especially longleaf pine, slash pine, bald cypress, and royal palm, that are on average 57 ft (17 m) in height and with an average 15-in (38-cm) dbh and that are emergent from the surrounding canopy (by an average 16 ft (5 m)); and

(b) Sufficient unobstructed space, with cavities averaging 35 ft (10.7 m) above the ground and roost trees averaging 14 ft (4 m) from the nearest tree, for Florida bonneted bats to emerge from roost trees; this may include open or semi-open canopy and canopy gaps.

(2) Habitats that provide adequate prey and space for foraging, which may vary widely across the Florida bonneted bat’s range, in accordance with ecological conditions, seasons, and disturbance regimes that influence vegetation structure and prey species’ distributions. Foraging habitat may be separate and relatively far from roosting habitat. Essential foraging habitat consists of open areas in or near areas

of high insect production or congregation, commonly including, but not limited to:

(a) Freshwater edges and freshwater herbaceous wetlands (permanent or seasonal);

(b) Prairies;

(c) Wetland and upland shrub; and/or

(d) Wetland and upland forests.

(3) A dynamic disturbance regime (e.g., fire, hurricanes, forest management) that maintains and regenerates forested habitat, including plant communities, open habitat structure, and temporary gaps, which is conducive to promoting a continual supply of roosting sites, prey items, and suitable foraging conditions.

(4) A sufficient quantity and diversity of habitats to enable the species to be resilient to short-term impacts associated with disturbance over time (e.g., drought, forest disease). This quantity and diversity are essential to provide suitable conditions despite temporary alterations to habitat quality. The ecological communities the Florida bonneted bat inhabits differ in hydrology, fire frequency/intensity, climate, prey species, roosting sites, and threats, and include, but are not limited to:

(a) Pine rocklands;

(b) Cypress communities (cypress swamps, strand swamps, domes, sloughs, ponds);

(c) Hydric pine flatwoods (wet flatwoods);

(d) Mesic pine flatwoods; and

(e) High pine.

(5) Habitats that provide structural connectivity where needed to allow for dispersal, gene flow, and natural and adaptive movements, including those that may be necessitated by climate change. These connections may include linear corridors such as vegetated, riverine, or open-water habitat with opportunities for roosting and/or foraging, or patches (i.e., stepping stones) such as tree islands or other isolated natural areas within a matrix of otherwise low-quality habitat.

(6) A subtropical climate that provides tolerable conditions for the species such that normal behavior, successful reproduction, and rearing of offspring are possible.

Special Management Considerations or Protection

When designating critical habitat, we assess whether the specific areas within the geographical area occupied by the species at the time of listing contain features which are essential to the conservation of the species and which may require special management considerations or protection. Recovery

of the Florida bonneted bat will require special management considerations or protection of the physical or biological features including passive (e.g., allowing natural processes to occur without intervention) and active (e.g., taking actions to restore and maintain habitat conditions or address threats) management. The features essential to the conservation of this species may require special management considerations or protection to reduce the threats that are related to inadvertent impacts from land management practices are discussed below. For discussion of special management considerations or protection required to reduce threats related to *Habitat Loss, Climate Change and Sea-level Rise, Environmental Stochasticity, and Pesticides and Contaminants*, see these sections in the proposed critical habitat rule (85 FR 35510, June 10, 2020).

Inadvertent Impacts From Land Management Practices

Forest management can help maintain and improve the Florida bonneted bat's roosting and foraging habitat (see *Use of Forests and Other Natural Areas* in the final listing rule (78 FR 61004, October 2, 2013, pp. 61007–61010)), and a lack of forest management, including a lack of prescribed fire, can be detrimental to the species. Prescribed burns may benefit Florida bonneted bats by improving habitat structure, enhancing the prey base, and creating openings; restoration of fire to fire-dependent forests may improve foraging habitat for this species and create snags (Carter et al. 2002, p. 139; Boyles and Aubrey 2006, pp. 111–113; Lacki et al. 2009, entire; Armitage and Ober 2012, pp. 107–109; FWC 2013, pp. 9–11; Ober and McCleery 2014, pp. 1–3; Braun de Torrez et al. 2018a–b, entire).

Fire is a vital component in maintaining suitable Florida bonneted bat habitat (Braun de Torrez et al. 2018b, entire), and while many prescribed fire and other land management practices mimic natural processes and benefit native species on broad spatial and temporal scales, these activities can result in inadvertent negative impacts in the near term. For example, extensive removal of trees with cavities or hollows during activities associated with forest management, fuel reduction, vista management, off-road vehicle trail maintenance, prescribed fire, or habitat restoration may inadvertently remove roost sites or reduce the availability of roost sites (see *Land Management Practices* in the final listing rule (78 FR 61004, October 2, 2013, p. 61027)).

Cavity-roosting bats may be susceptible to fire effects (Carter et al. 2002, p. 140). Loss of active roosts or removal during critical life-history stages (e.g., when females are pregnant or rearing young) is of greatest concern, given the species' apparent small population size and low fecundity (Bailey et al. 2017b, p. 556; see also *Effects of Small Population Size, Isolation, and Other Factors* in the final listing rule (78 FR 61004, October 2, 2013, pp. 61036–61037)). Risk from forest management may be minimized by conducting activities outside the bat's peak breeding season (April 15 to August 15), protecting known roost sites, or avoiding potential roost sites, as disturbance to roost sites at any time of the year may alter social dynamics and reproductive success (Blumstein 2010, pp. 665–666; Ober et al. 2017, p. 382). Special management considerations or protections to retain the essential physical or biological features for Florida bonneted bat include annual or seasonal monitoring efforts, or monitoring conducted prior to (but coordinated with) annual fire or forest management planning that can identify sensitive areas and incorporate appropriate avoidance or minimization measures. Developing additional avoidance or minimization measures for common management practices and activities (see the Florida Bonneted Bat Consultation Guidelines in Supporting Documents) on specific properties can also reduce negative effects. Retaining potential roost trees, wherever possible, may also reduce competition for tree cavities (see *Competition for Tree Cavities* in the final listing rule (78 FR 61004, October 2, 2013, pp. 61034–61035)), and promote survival and the potential for population expansion over the long term.

The features essential to the conservation of the Florida bonneted bat may require special management considerations or protection to reduce threats and conserve these features. Actions that could ameliorate threats include, but are not limited to:

(1) Retaining and actively managing a habitat network of large and diverse conservation lands throughout the Florida bonneted bat's range;

(2) Protecting, restoring, or enhancing inland or higher elevation habitats that are predicted to be unaffected or less affected by sea-level rise;

(3) Protecting habitats that support high insect diversity and abundance, and avoiding the excessive use of pesticides wherever possible;

(4) Retaining potential roost trees and snags (see *Cover or Shelter*, above);

(5) Conducting annual or seasonal monitoring efforts, or monitoring conducted prior to (but coordinated with) annual fire or forest management planning; and

(6) Developing and implementing specific guidelines (see the Florida Bonneted Bat Consultation Guidelines in Supporting Documents) to minimize impacts of activities associated with hurricane clean-up, prescribed fire, invasive species management, forest management, and development.

Special Management Previously Considered

In the June 10, 2020, proposed rule to designate critical habitat for the Florida bonneted bat (85 FR 35510), we considered ecological light pollution to be a potential threat to the Florida bonneted bat and its habitat that would likely require special management. However, as we described in the final listing rule, the Florida bonneted bat's behavioral response to ecological light pollution has not been examined, and effects are not known (78 FR 61004, October 2, 2013, p. 61036). The species' fast-flight and long-range flight capabilities may make it more able to exploit insects congregated at artificial light sources and more susceptible to risks associated with such responses (e.g., increased predation or harm from humans). Alternatively, artificial lighting may not be influencing the species' foraging or other behaviors. Accordingly, at this time, there continues to be little information about the potential effects of light pollution on the Florida bonneted bat.

Therefore, upon further review of the best available information, we have removed ecological light pollution as a potential threat to the species that may require special management considerations or protection, but we specifically request comments on this matter.

Conservation Strategy and Selection Criteria Used To Identify Critical Habitat

Conservation Strategy

As required by section 4(b)(2) of the Act, we use the best scientific data available to designate critical habitat. In accordance with the Act and our implementing regulations at 50 CFR 424.12(b), we review available information pertaining to the habitat requirements of the species and identify specific areas within the geographical area occupied by the species at the time of listing and any specific areas outside the geographical area occupied by the species to be considered for designation

as critical habitat. We are not currently proposing to designate any areas outside the geographical area occupied by the species because we have not identified any unoccupied areas that meet the definition of critical habitat. The occupied areas identified encompass the varying types and distribution of habitat needed by the species and provide sufficient habitat to allow for maintaining and potentially expanding the populations.

To determine and select appropriate occupied areas that contain the physical or biological features essential to the conservation of the species or areas otherwise essential for the conservation of the Florida bonneted bat, we incorporated information from the conservation strategy for the species. The goal of our conservation strategy for the Florida bonneted bat is to recover the species to the point where the protections of the Act are no longer necessary. The role of critical habitat in achieving this conservation goal is to identify the specific areas within the Florida bonneted bat's range that provide essential physical and biological features without which the Florida bonneted bat's rangewide resiliency, redundancy, and representation could not be achieved. Specifically, this conservation strategy helped identify those areas within the Florida bonneted bat's range that contain the physical and biological features without which rangewide resiliency, redundancy, and representation could not be achieved. Our conservation strategy identified goals, from which we developed the following six critical habitat criteria for determining the specific areas that contain the physical and biological features essential to the conservation of the species:

(1) Genetic diversity—To maintain viable populations in each of the known genetically differentiated areas (see *Space for Individual and Population Growth and for Normal Behavior*, above), critical habitat should include one unit within each of the four genetically differentiated populations.

(2) Geographic extent—To maintain viable populations that are distributed across the geographic range of the Florida bonneted bat (see *Current Distribution* in the final listing rule (78 FR 61004, October 2, 2013, pp. 61010–61011)), critical habitat units should represent the extent of the species' existing known range.

(3) Ecological diversity—To maintain at least one viable population in each major ecological community that provides roosting habitat for the Florida bonneted bat (see *Habitats with*

Appropriate Disturbance Regimes, above), these community types should be well represented in critical habitat units.

(4) Climate change resilience—To maintain at least one viable population in suitable habitat predicted to be unaffected or less affected by sea-level rise and climate change, critical habitat should include one unit in the northern, inland portion of the Florida bonneted bat's range.

(5) High conservation value (HCV) habitat—To maintain sufficient habitat with HCV that supports the life history of the species within each population, critical habitat units should incorporate multiple areas that support roosting and foraging needs and that have HCV (as informed by habitat analysis results and telemetry data).

(6) Structural connectivity—To maintain, enhance, and reestablish connectivity within and between Florida bonneted bat populations, critical habitat units should be configured within the central and south Florida landscape to provide connectivity based on the best available movement data for the species (see *Space for Individual and Population Growth and for Normal Behavior*, above).

Selection Criteria and Methodology Used To Identify Critical Habitat

To delineate the specific areas that are occupied by the species and that contain the physical and biological features essential to the Florida bonneted bat's conservation, we conducted a habitat analysis. Acknowledging some limitations in the information available, we used the best available data to conduct our habitat analysis (see Florida Bonneted Bat Habitat Analysis in Supporting Documents). Information used in the habitat analysis and/or the delineation of critical habitat units consists of the following:

(1) Confirmed presence data compiled in our Geographic Information System (GIS) database from 2003 through 2021, and provided by the Florida Fish and Wildlife Conservation Commission (FWC), University of Florida (UF), and other various sources, including survey reports, databases, and publications;

(2) Vegetation cover types from the Cooperative Land Cover map (CLC; version 3.4) developed by FWC and Florida Natural Areas Inventory;

(3) Canopy height from the global forest canopy height map (2019) developed by Global Land Analysis and Discovery;

(4) Red-cockaded woodpecker (*Picoides borealis*) potential habitat

(2016) developed by FWC, based on evidence indicating Florida bonneted bats use woodpecker cavities for roosting;

(5) Artificial sky luminance from the New World Atlas of Artificial Sky Brightness developed by the Light Pollution Science and Technology Institute (Falchi et al. 2016, entire);

(6) Fire frequency data provided by the Monitoring Trends in Burn Severity program;

(7) Urban development data (2010 baseline) from the Florida 2070 project developed by the Florida Department of Agriculture and Consumer Services, the UF GeoPlan Center, and 1000 Friends of Florida;

(8) Maps of unpublished telemetry data collected and provided by UF and FWC; and

(9) ArcGIS online basemap aerial imagery (2018–2020) to cross-check CLC data and ensure the presence of physical or biological features.

To help identify potential factors affecting Florida bonneted bat use, we conducted a spatial analysis to quantify relationships of habitat-related and other environmental variables with species occurrence (see the Florida Bonneted Bat Habitat Analysis in Supporting Documents)). Available presence data incorporated into the analysis primarily consisted of acoustic data, as well as locations of known roosts. Maps of telemetry locations were used to inform our evaluation of HCV areas but were not part of the habitat analysis dataset because coordinate data were not available at the time. We identified 10 covariates that related to habitat types (e.g., pine/cypress) and other factors (e.g., fire history) thought to influence habitat suitability and use by the Florida bonneted bat and modeled those at three spatial scales (see the Florida Bonneted Bat Habitat Analysis in Supporting Documents). Model output included predictive maps representing the probability of species occurrence based on the covariates included in the final models, and we used these maps to characterize the relative habitat suitability and conservation value of areas within central and south Florida. We also conducted sensitivity/specificity analyses to identify an objective threshold value for each model, which we then applied to identify areas with high conservation value to the species. See the Florida Bonneted Bat Habitat Analysis in Supporting Documents for full details of our methodology and results, including links to data sources used.

We considered the model output and the conservation strategy to determine

the specific areas occupied by the species on which are found the physical or biological features that are essential to the Florida bonneted bat. Those specific areas (critical habitat units) were identified and delineated using the following steps:

(1) We identified areas having high conservation value (as described above) for the Florida bonneted bat based on model output because those areas are likely to contain the combination of characteristics that we have determined are essential physical or biological features for the Florida bonneted bat.

(2) We refined these areas to eliminate any unsuitable or less suitable areas that are unlikely to contain features essential to the conservation of the species based on the Florida bonneted bat's biology (e.g., temperature requirements) and aerial imagery.

(3) We considered telemetry maps and certain critical habitat criteria that were not incorporated into the models (e.g., connectivity). Where telemetry maps indicated high use (e.g., HCV foraging habitat), or where additional area was needed to ensure sufficient connectivity, we delineated additional habitat using CLC data and aerial imagery and based on model output and covariate relationships identified in our habitat analysis.

(4) We evaluated the resulting units to determine whether occupied habitat is adequate to ensure conservation of the species. We specifically evaluated occupied units to ensure they fulfill all critical habitat criteria and meet the goals and objectives in our conservation strategy for identifying the areas that contain the features that are essential to the Florida bonneted bat. Based on our determination that occupied areas are sufficient for the conservation of the species, no unoccupied habitat is included in this revised proposed critical habitat designation.

When determining revised proposed critical habitat boundaries, we made every effort to avoid including developed areas such as lands covered by buildings, pavement, and other structures because such lands lack physical or biological features necessary for the Florida bonneted bat. The scale of the maps we prepared under the parameters for publication within the Code of Federal Regulations may not reflect the exclusion of such developed lands. Any such lands inadvertently left inside critical habitat boundaries shown on the maps of this proposed rule have been excluded by text in the proposed rule and are not proposed for designation as critical habitat. Therefore, if the critical habitat is finalized as proposed, a Federal action

involving these lands would not trigger section 7 consultation with respect to critical habitat and the requirement of no adverse modification unless the specific action would affect the physical or biological features in the adjacent critical habitat.

We propose to designate as critical habitat lands that we have determined are occupied at the time of listing (*i.e.*, currently occupied), that contain one or more of the physical or biological features that are essential to support life-history processes of the species, and that may require special management considerations or protection. We considered areas occupied at the time of listing if they have documented presence of Florida bonneted bats from October 2013 through 2021. Due to the species' life span and high site fidelity, it is reasonable to conclude that these areas found to be occupied in 2013 to 2021 would have been inhabited by Florida bonneted bats when the species was listed in 2013. Each unit we propose to designate as critical habitat contains all the identified physical or biological features essential to the conservation of the species.

The revised proposed critical habitat designation is defined by the map or maps, as modified by any accompanying regulatory text, presented at the end of this document under Proposed Regulation Promulgation. We include more detailed information on the boundaries of the critical habitat designation in the preamble of this document. We will make the coordinates or plot points or both on which each map is based available to the public on <https://www.regulations.gov> at Docket No. FWS-R4-ES-2019-0106 and at the Florida Ecological Services Field Office website at <https://www.fws.gov/office/florida-ecological-services/library>.

Revised Proposed Critical Habitat Designation

We are proposing to designate nine units as critical habitat for the Florida bonneted bat. The critical habitat areas we describe below constitute our best assessment of areas that meet the definition of critical habitat for the Florida bonneted bat. The nine areas we propose as critical habitat are: (1) Kissimmee Unit, (2) Peace River Unit, (3) Babcock Unit, (4) Fisheating Creek Unit, (5) Corkscrew Unit, (6) Big Cypress Unit, (7) Everglades Tree Islands Unit, (8) Long Pine Key Unit, and (9) Miami-Dade Rocklands Unit. All nine units proposed as critical habitat are occupied by the species. Table 1 shows the revised proposed critical habitat units and the approximate area

of each unit/subunit within each land ownership category.

TABLE 1—REVISED PROPOSED CRITICAL HABITAT UNITS AND SUBUNITS FOR THE FLORIDA BONNETED BAT, INCLUDING ACRES (ac) AND HECTARES (ha) BY LAND OWNERSHIP CATEGORY

[Area estimates reflect all land within critical habitat unit boundaries, and land ownership was determined using the most recent parcel data provided by each county. All units are occupied]

Critical habitat unit/subunit	Land ownership: ac (ha)							Total area: ac (ha)
	Federal	Tribal	State	County	Local	Private/other	Unidentified	
1. Kissimmee	99 (40)	1 (<1)	135,779 (54,948)	815 (330)	0	36,996 (14,972)	2,047 (828)	175,737 (71,118)
1A	90 (36)	0	135,343 (54,771)	612 (248)	0	31,241 (12,643)	2,047 (828)	169,331 (68,526)
1B	9 (4)	1 (<1)	437 (177)	203 (82)	0	5,755 (2,329)	0	6,405 (2,592)
2. Peace River	32 (13)	0	6,389 (2,586)	563 (228)	165 (67)	19,047 (7,708)	1,850 (749)	28,046 (11,350)
2A	0	0	0	0	0	2,603 (1,053)	0	2,603 (1,053)
2B	0	0	0	0	0	5,478 (2,217)	200 (81)	5,678 (2,298)
2C	0	0	0	0	0	2,029 (821)	2 (1)	2,031 (822)
2D	32 (13)	0	6,389 (2,586)	563 (228)	165 (67)	8,938 (3,617)	1,648 (667)	17,734 (7,177)
3. Babcock	0	0	108,509 (43,912)	782 (316)	19 (8)	23,929 (9,684)	322 (130)	133,560 (54,050)
3A	0	0	80,043 (32,392)	782 (316)	19 (8)	7,392 (2,991)	322 (130)	88,559 (35,839)
3B	0	0	28,466 (11,520)	0	0	16,536 (6,692)	0	45,001 (18,211)
4. Fisheating Creek	0	0	7,689 (3,112)	<1	0	5,300 (2,145)	6 (2)	12,995 (5,259)
5. Corkscrew	0	0	26,226 (10,613)	5,265 (2,131)	13 (5)	17,319 (7,009)	41 (17)	48,865 (19,775)
6. Big Cypress	533,179 (215,770)	14,455 (5,850)	152,494 (61,712)	8,419 (3,407)	229 (93)	16,170 (6,544)	3,598 (1,456)	728,544 (294,831)
7. Everglades Tree Islands	16,538 (6,693)	0	1 (<1)	4 (2)	0	<1	60 (24)	16,604 (6,719)
8. Long Pine Key	25,142 (10,175)	0	2 (1)	0	0	187 (76)	5 (2)	25,337 (10,254)
9. Miami Rocklands	599 (242)	0	796 (322)	2,403 (972)	8 (3)	471 (190)	46 (19)	4,324 (1,750)
9A	0	0	0	52 (21)	0	<1	1 (<1)	53 (21)
9B	0	0	0	104 (42)	0	<1	1 (<1)	104 (42)
9C	0	0	0	5 (2)	0	<1	<1	5 (2)
9D	0	0	10 (4)	0	0	18 (7)	1 (<1)	28 (11)
9E	0	0	21 (8)	230 (93)	<1	13 (5)	2 (1)	267 (108)
9F	140 (57)	0	0	<1	0	<1	<1	140 (57)
9G	0	0	8 (3)	0	0	19 (8)	<1	28 (11)
9H	0	0	235 (95)	0	0	<1	3 (1)	238 (96)
9I	0	0	0	22 (9)	0	<1	<1	22 (9)
9J	0	0	60 (24)	<1	8 (3)	28 (11)	3 (1)	99 (40)
9K	0	0	36 (15)	<1	0	<1	<1	37 (15)
9L	0	0	77 (31)	<1	<1	<1	<1	77 (31)
9M	0	0	0	114 (46)	0	<1	<1	114 (46)
9N	0	0	18 (7)	0	0	<1	<1	18 (7)
9O	458 (185)	0	0	1,180 (478)	0	123 (50)	1 (<1)	1,762 (713)
9P	0	0	48 (19)	0	0	13 (5)	<1	61 (25)
9Q	0	0	<1	7 (3)	0	7 (3)	<1	14 (6)
9R	0	0	36 (15)	22 (9)	0	13 (5)	8 (3)	80 (32)
9S	0	0	34 (14)	63 (25)	0	35 (14)	2 (1)	135 (55)
9T	0	0	10 (4)	0	0	25 (10)	<1	36 (15)
9U	0	0	18 (7)	4 (2)	0	1 (<1)	<1	23 (9)
9V	0	0	0	0	0	30 (12)	1 (<1)	31 (13)
9W	0	0	9 (4)	103 (42)	0	<1	<1	112 (45)
9X	0	0	0	10 (4)	0	20 (8)	<1	30 (12)
9Y	0	0	0	18 (7)	0	11 (4)	4 (2)	32 (13)
9Z	0	0	0	28 (11)	0	<1	3 (1)	31 (13)
9AA	0	0	22 (9)	24 (10)	0	37 (15)	<1	84 (34)
9BB	0	0	0	19 (8)	0	23 (9)	1 (<1)	43 (17)
9CC	0	0	0	9 (4)	0	15 (6)	<1	24 (10)
9DD	0	0	19 (8)	0	0	<1	<1	19 (8)
9EE	0	0	12 (5)	<1	0	1 (<1)	5 (2)	18 (7)
9FF	0	0	0	39 (16)	0	<1	<1	39 (16)
9GG	0	0	81 (33)	240 (97)	0	28 (11)	1 (<1)	351 (142)
9HH	0	0	22 (9)	0	0	<1	<1	22 (9)
9II	0	0	18 (7)	5 (2)	0	10 (4)	6 (2)	39 (16)
9JJ	<1	0	0	105 (42)	0	<1	2 (1)	108 (44)
Total	575,589 (232,933)	14,457 (5,851)	437,888 (177,207)	18,251 (7,386)	434 (176)	119,419 (48,327)	7,974 (3,227)	1,174,011 (475,105)

Note: Area sizes may not sum due to rounding.

We present brief descriptions of all units, and reasons why they meet the definition of critical habitat for the Florida bonneted bat, below.

Unit 1: Kissimmee Unit

Unit 1 encompasses 175,737 ac (71,118 ha) of lands in Polk, Osceola, Highlands, and Okeechobee Counties, Florida. This unit consists of two subunits generally located along the eastern bank of Lake Kissimmee northeast to SR-192, north of SR-60; and along portions of the Kissimmee River, south of SR-60. Unit 1 predominately consists of State-owned conservation lands (135,779 ac (54,948 ha)) and private lands (36,996 ac (14,972 ha)). The largest conservation landholdings within this unit include Kissimmee Prairie Preserve State Park, Three Lakes WMA, Herky Huffman/Bull Creek WMA, Triple N Ranch WMA, and South Florida Water Management District lands along the Kissimmee River. Other smaller conservation lands also occur within this unit (for more information, see the Conservation Lands document in Supporting Documents).

Unit 1 contains all of the essential physical or biological features for the Florida bonneted bat and is considered occupied at the time of listing based on documented presence of Florida bonneted bats within the unit. The Kissimmee Unit represents the northern extent of the species' range and provides resiliency against the expected impacts from habitat loss due to climate change as it includes areas considered less vulnerable to these effects. Habitat in this unit provides ecological diversity (*i.e.*, high pine and mesic flatwoods) and includes areas identified as having HCV, specifically high-quality roosting habitat (*e.g.*, potential roost trees, red-cockaded woodpecker activity in the area) and foraging habitat (*e.g.*, open water, abundant prey). In addition, the Florida bonneted bats in this area are genetically differentiated from those occurring elsewhere in the range (Austin et al. 2022, entire), and thus contribute to the genetic diversity of the overall population.

The physical or biological features essential to the conservation of the Florida bonneted bat in Unit 1 may require special management considerations or protection due to the following threats: Habitat loss and fragmentation from changes in land use (*e.g.*, land clearing for residential/commercial development); lack of habitat management and/or inadvertent impacts from these habitat management practices (*e.g.*, prescribed fire, snag removal); and excessive pesticide use

(see Special Management Considerations or Protection, above).

Under section 4(a)(3)(B)(i) of the Act, we are exempting Avon Park Air Force Range lands (99,523 ac (40,276 ha)) from the critical habitat designation because the U.S. Air Force has an approved integrated natural resources management plan (INRMP) that provides benefits to the Florida bonneted bat and its habitat (see Exemptions, below, for more detailed information).

Approximately 1.25 ac (0.5 ha) of Tribal lands occur within Unit 1 (Miccosukee Tribe of Florida). We are considering exclusion of these lands from the final critical habitat designation under section 4(b)(2) of the Act (see *Consideration of Other Relevant Impacts*, below).

Unit 2: Peace River Unit

Unit 2 encompasses 28,046 ac (11,350 ha) of lands in Hardee, DeSoto, and Charlotte Counties, Florida. This unit consists of four subunits located along portions of the Peace River and its tributaries (*e.g.*, Shell Creek, Charlie Creek), south of CR-64 with the majority west of U.S.-17. Unit 2 predominately consists of privately owned lands (19,047 ac (7,708 ha)) and State-owned conservation lands (6,389 ac (2,586 ha)). The largest conservation landholdings within this unit include the Peace River State Forest and the Deep Creek Preserve. Other smaller conservation lands also occur within this unit (for more information, see the Conservation Lands document in Supporting Documents).

Unit 2 contains all of the essential physical or biological features for the Florida bonneted bat and is considered occupied at the time of listing based on documented presence of Florida bonneted bats within the unit. The Peace River Unit encompasses a known movement corridor (generally connecting proposed Units 1 and 3), allowing gene flow between these populations, and includes areas identified as having HCV, specifically high-quality foraging habitat along the Peace River and adjacent forested lands that provide open water and abundant prey. In addition, this unit adds ecological diversity (a natural river corridor) to the overall proposed designation.

The physical or biological features essential to the conservation of the Florida bonneted bat in Unit 2 may require special management considerations or protection due to the following threats: Habitat loss, fragmentation, or degradation from changes in land use (*e.g.*, land clearing

for residential/commercial development); lack of habitat management and/or inadvertent impacts from land management practices (*e.g.*, prescribed fire, snag removal); excessive pesticide use; and climate change (*e.g.*, sea level rise/inundation, saltwater intrusion, habitat alteration/degradation) (see Special Management Considerations or Protection, above).

Unit 3: Babcock Unit

Unit 3 encompasses 133,560 ac (54,050 ha) of lands in Charlotte, Lee, and Glades Counties, Florida. This unit consists of two subunits, with the majority of Unit 3 located in Charlotte County, east of I-75; other portions are in northwestern Lee and western Glades Counties. This unit predominately consists of State-owned conservation lands (108,509 ac (43,912 ha)) and private lands (23,929 ac (9,684 ha)). The largest conservation landholdings within this unit are Babcock-Webb WMA and Babcock Ranch Preserve; other smaller conservation lands also occur within this unit (for more information, see the Conservation Lands document in Supporting Documents).

Unit 3 contains all of the essential physical or biological features for the Florida bonneted bat and is considered occupied at the time of listing based on documented presence of Florida bonneted bats within the unit. Habitat in the Babcock Unit provides ecological diversity (*i.e.*, hydric and mesic flatwoods) and includes areas identified as having HCV, specifically superior roosting and foraging habitat. Babcock-Webb WMA and surrounding areas support the largest known population of Florida bonneted bats and the majority of all known roost sites. In addition, the Florida bonneted bats in this westernmost extent of the species' range are genetically differentiated from those occurring elsewhere in the range (Austin et al. 2022, entire), thus contributing to the genetic diversity of the overall population.

The physical or biological features essential to the conservation of the Florida bonneted bat in Unit 3 may require special management considerations or protection due to the following threats: Habitat loss, fragmentation, or degradation from changes in land use (*e.g.*, land clearing for residential/commercial development); lack of habitat management and/or inadvertent impacts from land management practices (*e.g.*, prescribed fire, snag removal); excessive pesticide use; and climate change (*e.g.*, sea level rise/inundation, saltwater intrusion, habitat alteration/

degradation) (see Special Management Considerations or Protection, above).

Unit 4: Fisheating Creek Unit

Unit 4 encompasses 12,995 ac (5,259 ha) of lands in Glades and Highlands Counties, Florida. The majority of Unit 4 is located in Glades County, west of US-27; the remaining portion of the unit extends north into southern Highlands County. This unit predominately consists of State-owned conservation lands (7,689 ac (3,112 ha)) and private lands (5,300 ac (2,145 ha)). Conservation landholdings within this unit are Fisheating Creek WMA, Fisheating Creek/Lykes Brothers Conservation Easement, and Platt Branch Wildlife and Environmental Area.

Unit 4 contains all of the essential physical or biological features for the Florida bonneted bat and is considered occupied at the time of listing based on documented presence of Florida bonneted bats within the unit. High-quality foraging habitat along Fisheating Creek and adjacent forested lands provide open water and abundant prey. This unit serves as important foraging habitat connecting bats traveling between proposed Unit 3 and areas to the north and east, and, along with proposed Unit 2, this unit adds ecological diversity (natural river corridors) to the overall proposed designation.

The physical or biological features essential to the conservation of the Florida bonneted bat in Unit 4 may require special management considerations or protection due to the following threats: Habitat loss, fragmentation, or degradation from changes in land use (e.g., land clearing for residential/commercial development); lack of habitat management and/or inadvertent impacts from land management practices (e.g., prescribed fire, snag removal, hydrologic restoration); excessive pesticide use; and climate change (e.g., sea level rise/inundation, saltwater intrusion, habitat alteration/degradation) (see Special Management Considerations or Protection, above).

Unit 5: Corkscrew Unit

Unit 5 encompasses 48,865 ac (19,775 ha) of lands in Lee and Collier Counties, Florida. This unit straddles the Lee/Collier county line, east of I-75, and predominately consists of State-owned conservation lands (26,226 ac (10,613 ha)) and private lands (17,319 ac (7,009 ha)). The largest conservation landholdings within this unit are Corkscrew Regional Ecosystem Watershed and the National Audubon

Society's Corkscrew Swamp Sanctuary; other smaller conservation lands also occur within this unit (for more information, see the Conservation Lands document in Supporting Documents).

Unit 5 contains all of the essential physical or biological features for the Florida bonneted bat and is considered occupied at the time of listing based on documented presence of Florida bonneted bats within the unit. Habitat within the Corkscrew Unit provides ecological diversity (i.e., cypress and hydric flatwoods) and includes areas identified as having HCV. Corkscrew Swamp Sanctuary was established to protect one of the largest remaining stands of cypress in North America, and this area likely includes high-quality roosting habitat. The area also provides connectivity between Babcock-Webb WMA and areas south. The natural habitat within Unit 5 serves as important habitat in an area that is otherwise under high development pressure.

The physical or biological features essential to the conservation of the Florida bonneted bat in Unit 5 may require special management considerations or protection due to the following: Habitat loss, fragmentation, or degradation from changes in land use (e.g., land clearing for residential/commercial development); lack of habitat management and/or inadvertent impacts from land management practices (e.g., prescribed fire, snag removal); and climate change (e.g., sea level rise/inundation, saltwater intrusion, habitat alteration/degradation) (see Special Management Considerations or Protection, above).

Unit 6: Big Cypress Unit

Unit 6 encompasses 728,544 ac (294,831 ha) of lands in Collier, Hendry, and Monroe Counties, Florida. The majority of Unit 6 is located in Collier County, south of I-75; the remainder occurs in southern Hendry County and mainland portions of Monroe County. This unit predominately consists of Federal (533,179 ac (215,770 ha)) and State-owned (152,494 ac (61,712 ha)) conservation lands. The largest landholdings within this unit are Big Cypress National Preserve, Florida Panther National Wildlife Refuge (NWR), Fakahatchee Strand Preserve State Park, and Picayune Strand State Forest; other smaller conservation lands also occur within this unit (for more information, see the Conservation Lands document in Supporting Documents).

Unit 6 contains all of the essential physical or biological features for the Florida bonneted bat and is considered occupied at the time of listing based on

documented presence of Florida bonneted bats within the unit. Habitat in the Big Cypress Unit, along with Unit 5, provides ecological diversity (i.e., cypress and hydric flatwoods) and includes areas identified as having HCV. Roosting habitat within this unit is of particularly high quality. Despite challenges in accessing this site to conduct surveys, the Florida bonneted bat has been documented throughout this unit, including the discovery of 25 natural roosts (the most of any unit). The Florida bonneted bats in this area are genetically differentiated from those occurring elsewhere in the range (Austin et al. 2022, entire) and thus contribute to the genetic diversity of the overall population.

The physical or biological features essential to the conservation of the Florida bonneted bat in Unit 6 may require special management considerations or protection due to the following threats: Habitat loss, fragmentation, or degradation from changes in land use (e.g., land clearing for residential, commercial, transportation, or energy-related development); lack of habitat management and/or inadvertent impacts from land management practices (e.g., prescribed fire, snag removal, habitat and hydrologic restoration); excessive pesticide use; and climate change (e.g., sea level rise/inundation, saltwater intrusion, habitat alteration/degradation, coastal squeeze) (see Special Management Considerations or Protection, above).

Approximately 14,455 ac (5,850 ha) of Tribal lands occur within Unit 6 (Seminole Tribe of Florida). We are considering exclusion of these lands from the final critical habitat designation under section 4(b)(2) of the Act (see *Consideration of Other Relevant Impacts*, below).

Unit 7: Everglades Tree Islands Unit

Unit 7 encompasses 16,604 ac (6,719 ha) of lands in Miami-Dade County, Florida, south of Tamiami Trail and west of Krome Avenue. Nearly this entire unit is Federal land within Everglades National Park (ENP; 16,538 ac (6,693 ha)).

Unit 7 contains all of the essential physical or biological features for the Florida bonneted bat and is considered occupied at the time of listing based on documented presence of Florida bonneted bats within the unit. The Everglades Tree Islands Unit provides connectivity between Unit 6 and the southeast coast (proposed Units 8 and 9), allowing gene flow between these populations. It also includes areas identified as having HCV. Despite

limited effort and challenges accessing the area to conduct surveys, the Florida bonneted bat has been documented throughout this unit.

The physical or biological features essential to the conservation of the Florida bonneted bat in Unit 7 may require special management considerations or protection due to the following threats: Lack of habitat management and/or inadvertent impacts from land management practices (*e.g.*, prescribed fire, snag removal, habitat and hydrologic restoration) and climate change (*e.g.*, sea level rise/inundation, saltwater intrusion, habitat alteration/degradation) (see Special Management Considerations or Protection, above).

Unit 8: Long Pine Key Unit

Unit 8 encompasses 25,337 ac (10,254 ha) of lands in Miami-Dade County, Florida, along ENP's Main Park Road (SR-9336) between Mahogany Hammock and SW 237th Avenue. Nearly this entire unit is Federal land within ENP (25,142 ac (10,175 ha)).

Unit 8 contains all of the essential physical or biological features for the Florida bonneted bat and is considered occupied at the time of listing based on documented presence of Florida bonneted bats within the unit. Habitat in the unit provides ecological diversity (*i.e.*, pine rocklands) and includes areas identified as having HCV, specifically high-quality roosting and foraging habitat within Long Pine Key, the largest remaining contiguous occurrence of pine rockland habitat. This unit includes the southernmost extent of the species' range and provides additional connectivity between proposed Units 6 and 9.

The physical or biological features essential to the conservation of the Florida bonneted bat in Unit 8 may require special management considerations or protection due to the following: Lack of habitat management and/or inadvertent impacts from land management practices (*e.g.*, prescribed fire, snag removal) and climate change (*e.g.*, sea level rise/inundation, saltwater intrusion, habitat alteration/degradation) (see Special Management Considerations or Protection, above).

Unit 9: Miami Rocklands Unit

Unit 9 encompasses 4,324 ac (1,750 ha) of lands in Miami-Dade County, Florida. This unit consists of 36 subunits located between Tamiami Trail to the north and SR-9336 to the south, and is surrounded by a dense urban matrix typical of the Miami metropolitan area. This unit predominately consists of conservation lands owned by county (2,403 ac (972

ha)), State (796 ac (322 ha)), and Federal (599 ac (242 ha)) agencies. The largest landholdings within this unit are Zoo Miami, Larry and Penny Thompson Park, the U.S. Coast Guard Communication Station, Navy Wells, and the Deering Estate. Many county-owned preserves and parks, as well as other smaller conservation lands, also occur within this unit (for more information, see the Conservation Lands document in Supporting Documents).

Unit 9 contains all of the essential physical or biological features for the Florida bonneted bat and is considered occupied at the time of listing based on documented presence of Florida bonneted bats within the unit. The Miami Rocklands Unit represents the easternmost extent of the species' range. Habitat in this unit provides ecological diversity (*i.e.*, pine rocklands) and includes areas identified as having HCV. This unit includes remaining fragments of pine rockland and rockland hammock habitat within an urbanized landscape. These fragments of natural habitat are used extensively by Florida bonneted bats and provide connectivity within the unit. Florida bonneted bats inhabiting the area are the most genetically differentiated from those occurring elsewhere in the range (Austin et al. 2022, entire), and thus contribute to the genetic diversity of the overall population.

The physical or biological features essential to the conservation of the Florida bonneted bat in Unit 9 may require special management considerations or protection due to the following: Habitat loss, fragmentation, or degradation from changes in land use (*e.g.*, land clearing for residential, commercial, transportation, or energy-related development); lack of habitat management and/or inadvertent impacts from land management practices (*e.g.*, prescribed burns, snag removal, habitat restoration); excessive pesticide use; and climate change (*e.g.*, sea level rise/inundation, saltwater intrusion, habitat alteration/degradation, coastal squeeze) (see Special Management Considerations or Protection, above).

Under section 4(a)(3)(B)(i) of the Act, we are exempting Homestead Air Reserve Base (Base) lands (280 ac (113 ha)) from critical habitat designation because the U.S. Air Force has an approved INRMP that provides benefits to the Florida bonneted bat and its habitat (see Exemptions, below, for more detailed information).

Approximately 104 ac (42 ha) of private lands under a habitat conservation plan (HCP) occur within Unit 9. We are considering exclusion of these lands from the final critical habitat

designation under section 4(b)(2) of the Act (see *Consideration of Other Relevant Impacts*, below).

Effects of Critical Habitat Designation

Section 7 Consultation

Section 7(a)(2) of the Act requires Federal agencies, including the Service, to ensure that any action they fund, authorize, or carry out is not likely to jeopardize the continued existence of any endangered species or threatened species or result in the destruction or adverse modification of designated critical habitat of such species. In addition, section 7(a)(4) of the Act requires Federal agencies to confer with the Service on any agency action which is likely to jeopardize the continued existence of any species proposed to be listed under the Act or result in the destruction or adverse modification of proposed critical habitat.

We published a final rule revising the definition of destruction or adverse modification on August 27, 2019 (84 FR 44976). Destruction or adverse modification means a direct or indirect alteration that appreciably diminishes the value of critical habitat as a whole for the conservation of a listed species.

If a Federal action may affect a listed species or its critical habitat, the responsible Federal agency (action agency) must enter into consultation with us. Examples of actions that are subject to the section 7 consultation process are actions on State, Tribal, local, or private lands that require a Federal permit (such as a permit from the U.S. Army Corps of Engineers under section 404 of the Clean Water Act (33 U.S.C. 1251 *et seq.*) or a permit from the Service under section 10 of the Act) or that involve some other Federal action (such as funding from the Federal Highway Administration, Federal Aviation Administration, or the Federal Emergency Management Agency). Federal actions not affecting listed species or critical habitat—and actions on State, Tribal, local, or private lands that are not federally funded, authorized, or carried out by a Federal agency—do not require section 7 consultation.

Compliance with the requirements of section 7(a)(2) is documented through our issuance of:

(1) A concurrence letter for Federal actions that may affect, but are not likely to adversely affect, listed species or critical habitat; or

(2) A biological opinion for Federal actions that may affect, and are likely to adversely affect, listed species or critical habitat.

When we issue a biological opinion concluding that a project is likely to jeopardize the continued existence of a listed species and/or destroy or adversely modify critical habitat, we provide reasonable and prudent alternatives to the project, if any are identifiable, that would avoid the likelihood of jeopardy and/or destruction or adverse modification of critical habitat. We define “reasonable and prudent alternatives” (at 50 CFR 402.02) as alternative actions identified during consultation that:

(1) Can be implemented in a manner consistent with the intended purpose of the action,

(2) Can be implemented consistent with the scope of the Federal agency’s legal authority and jurisdiction,

(3) Are economically and technologically feasible, and

(4) Would, in the Service Director’s opinion, avoid the likelihood of jeopardizing the continued existence of the listed species and/or avoid the likelihood of destroying or adversely modifying critical habitat.

Reasonable and prudent alternatives can vary from slight project modifications to extensive redesign or relocation of the project. Costs associated with implementing a reasonable and prudent alternative are similarly variable.

Regulations at 50 CFR 402.16 set forth requirements for Federal agencies to reinstate formal consultation on previously reviewed actions. These requirements apply when the Federal agency has retained discretionary involvement or control over the action (or the agency’s discretionary involvement or control is authorized by law) and, if subsequent to the previous consultation: (1) If the amount or extent of taking specified in the incidental take statement is exceeded; (2) if new information reveals effects of the action that may affect listed species or critical habitat in a manner or to an extent not previously considered; (3) if the identified action is subsequently modified in a manner that causes an effect to the listed species or critical habitat that was not considered in the biological opinion; or (4) if a new species is listed or critical habitat designated that may be affected by the identified action. In such situations, Federal agencies sometimes may need to request reinitiation of consultation with us, but the regulations also specify some exceptions to the requirement to reinstate consultation on specific land management plans after subsequently listing a new species or designating new critical habitat. See the regulations for a description of those exceptions.

Application of the “Destruction or Adverse Modification” Standard

The key factor related to the destruction or adverse modification determination is whether implementation of the proposed Federal action directly or indirectly alters the designated critical habitat in a way that appreciably diminishes the value of the critical habitat as a whole for the conservation of the listed species. As discussed above, the role of critical habitat is to support physical or biological features essential to the conservation of a listed species and provide for the conservation of the species. Factors considered in making these determinations may include the extent of the proposed action, including its temporal and spatial scale relative to the critical habitat unit or subunit within which it occurs; the specific purpose for which that unit or subunit was identified and designated as critical habitat; and the impact of the proposed action on the unit or subunit’s likelihood of serving its intended conservation function or purpose.

Section 4(b)(8) of the Act requires us to briefly evaluate and describe, in any proposed or final regulation that designates critical habitat, activities involving a Federal action that may violate section 7(a)(2) of the Act by destroying or adversely modifying such habitat, or that may be affected by such designation.

Activities that the Service may, during a consultation under section 7(a)(2) of the Act, consider likely to destroy or adversely modify critical habitat include, but are not limited to:

(1) Actions that would significantly alter roosting or foraging habitat or habitat connectivity such that they appreciably diminish the value of critical habitat as a whole. Such activities may include, but are not limited to: Land clearing for residential, commercial, transportation, energy-related or other development; and water diversion, drainage, or wetland loss or conversion. These activities could destroy Florida bonneted bat roosting and foraging sites (necessary for food, shelter, protection from predation, and reproduction); reduce habitat conditions below what is necessary for survival and growth; and/or eliminate or reduce the habitat necessary for successful reproduction, dispersal, and population expansion (see Physical or Biological Features Essential to the Conservation of the Species, above).

(2) Actions that would significantly alter vegetation structure or composition such that they appreciably diminish the value of critical habitat as a whole. Such

activities could include, but are not limited to: Habitat management or restoration (e.g., prescribed burning and other forest management activities, snag removal, or hydrologic restoration) conducted in a manner that does not minimize disturbance to the physical and biological features. These activities could affect habitat that provides for the Florida bonneted bat’s roosting and rearing, foraging and prey, refuge from short-term changes to habitat, and/or protection from predation (see Physical or Biological Features Essential to the Conservation of the Species, above).

(3) Actions that would significantly reduce suitability of habitat or impact prey base (e.g., availability, abundance, density, diversity) such that they appreciably diminish the value of critical habitat as a whole. These actions include, but are not limited to:

Hydrologic alteration or excessive pesticide applications that impact prey or alter foraging behavior or movement. These activities could significantly modify habitat that currently provides adequate prey and space for foraging (see Physical or Biological Features Essential to the Conservation of the Species, above).

Activities that the Service may, during a consultation under section 7(a)(2) of the Act, consider likely to adversely affect critical habitat but not likely to destroy or adversely modify critical habitat include actions that significantly affect the unit or subunit’s ability to fulfill its primary functions (e.g., connectivity, foraging or roosting habitat, genetic representation), but do not appreciably diminish the value of critical habitat as a whole. Such activities may include a landscape-scale hydrologic restoration project that would convert large amounts of roosting habitat to foraging habitat within a unit; development that would eliminate a small amount of high-value foraging area or affect a known corridor; or habitat or invasive species management programs that are overall beneficial to Florida bonneted bat habitat but may result in inadvertent, but significant, impacts to roosting habitat.

As noted above, some actions that are beneficial to Florida bonneted bat habitat, including actions necessary to maintain habitat quality and suitability, may result in inadvertent negative effects. When conducted with guidance from the Service or using established best management practices (BMPs) that prevent or minimize impacts, these actions are beneficial and are encouraged as a part of standard land management practices. Avoidance and minimization measures can also reduce the impacts of habitat loss and other

impacts from development projects, habitat alteration, and habitat conversion. General guidance has already been developed and is in use (see Florida Bonneted Bat Consultation Guidelines, Appendices D and E and Florida Bonneted Bat Avoidance and Minimization Measures in Supporting Documents); additional guidance is under development to address habitat management practices on conservation lands.

Some activities that the Service may consider to be activities that may affect, but are unlikely to adversely affect, critical habitat include actions that are wholly beneficial (*i.e.*, those that maintain, improve, or restore the functionality of critical habitat for the Florida bonneted bat without causing adverse effects to the essential physical or biological features), discountable (*i.e.*, unlikely to occur), or insignificant. In such cases, the Act's section 7 consultation requirements can be satisfied through the informal concurrence process.

Whether an action will have insignificant effects must be considered within the context of the unit or subunit in which the action occurs. A localized reduction in roosting or foraging habitat within a stand may have such a small impact on physical and biological features within the stand that a "not likely to adversely affect" determination is appropriate. Similarly, effects to roosting habitat may be negligible where a hazard tree removal project occurs in a stand with many suitable roosting trees.

Exemptions

Application of Section 4(a)(3) of the Act

The Sikes Act Improvement Act of 1997 (Sikes Act) (16 U.S.C. 670a) required each military installation that includes land and water suitable for the conservation and management of natural resources to complete an INRMP by November 17, 2001. An INRMP integrates implementation of the military mission of the installation with stewardship of the natural resources found on the base. Each INRMP includes:

- (1) An assessment of the ecological needs on the installation, including the need to provide for the conservation of listed species;
- (2) A statement of goals and priorities;
- (3) A detailed description of management actions to be implemented to provide for these ecological needs; and
- (4) A monitoring and adaptive management plan.

Among other things, each INRMP must, to the extent appropriate and

applicable, provide for fish and wildlife management; fish and wildlife habitat enhancement or modification; wetland protection, enhancement, and restoration where necessary to support fish and wildlife; and enforcement of applicable natural resource laws.

The National Defense Authorization Act for Fiscal Year 2004 (Pub. L. 108–136) amended the Act to limit areas eligible for designation as critical habitat. Specifically, section 4(a)(3)(B)(i) of the Act (16 U.S.C. 1533(a)(3)(B)(i)) provides that the Secretary shall not designate as critical habitat any lands or other geographical areas owned or controlled by the Department of Defense, or designated for its use, that are subject to an INRMP prepared under section 101 of the Sikes Act (16 U.S.C. 670a), if the Secretary determines in writing that such plan provides a benefit to the species for which critical habitat is proposed for designation.

We consult with the military on the development and implementation of INRMPs for installations with listed species. We analyzed INRMPs developed by military installations located within the range of the proposed critical habitat designation for the Florida bonneted bat to determine if they meet the criteria for exemption from critical habitat under section 4(a)(3) of the Act. The following areas are Department of Defense (DoD) lands with completed, Service-approved INRMPs within the proposed critical habitat designation.

Approved INRMPs

For discussion of the approved INRMP for Avon Park Air Force Range (Unit 1: Kissimmee Unit; 99,523 ac (40,276 ha)), see the Exemptions section in the proposed critical habitat rule (85 FR 35510, June 10, 2020).

Homestead Air Reserve Base (Unit 9: Miami Rocklands Unit—Subunits KK, LL), 280 ac (113 ha)

The Homestead Air Reserve Base (Base) has a current and completed INRMP, signed by the Service and the FWC in 2017 and 2018, respectively. The INRMP (U.S. Air Force Reserve Command (Air Force) 2016) provides conservation measures for the species and management of important upland and wetland habitats on the base.

The Base's INRMP provides benefits to Florida bonneted bat habitat as the primary goals of the plan include, "conservation and enhancement of the land and water resources of the Base and improving and maintaining the quality of native vegetation communities and threatened and endangered species' habitats, while supporting the military mission" (Air

Force 2016, p. 75). Some objectives identified under this goal that should benefit the Florida bonneted bat include: (1) Protecting, enhancing, and maintaining natural communities to support native fish and wildlife species; (2) conserving and protecting the habitats for federally and State-listed species; (3) reducing and controlling populations of invasive and exotic plant species; and (4) instituting control for nuisance and exotic wildlife.

More specifically, protecting and maintaining wetland functions, restoring pine rockland, controlling invasive species, managing water quality, and maintaining and enhancing natural habitat values and ecosystem functions are expected to benefit the species and its habitat. The Base's INRMP also includes specific projects to benefit the species including incorporation of Florida bonneted bat management strategies into conservation programs on the Base, working with the Service to identify and implement management strategies for foraging and roosting habitat, and conducting a qualitative bat survey (Air Force 2016, pp. A–3, A–4). The study is expected to provide information on the bat species present and their habitat use on the Base. Data from the study will be used to supplement and update existing natural resource management plans on the Base. Other components of the Base's INRMP, such as the Integrated Pest Management Plan, the Bird/Wildlife Aircraft Strike Hazard Plan, the threatened and endangered species training course, and implementation of the pine rockland restoration and management plan, have the potential to reduce pesticide use and exposure to bats, avoid aircraft strikes to bats, raise awareness about bats using the base, and enhance habitat quality for bats and other species (Air Force 2016, appendix A).

In addition, the Base's INRMP includes a management plan for the Florida bonneted bat that addresses: Conservation of wetlands to promote foraging opportunities; promotion of insect diversity and availability through the appropriate application of insecticides, mowing, and other maintenance practices; and protection of roosting habitat as identified through monitoring (Air Force 2016, appendix G). Per the management plan, guidelines outlined in the Base's INRMP, Pest Management Plan, Landscape Maintenance Plan, and the Protected Plant Management Plan will be closely monitored and adapted as life-history data for the Florida bonneted bat become available. The INRMP also includes proposed monitoring

consisting of acoustic surveys and more intensive surveys for roost sites; the Base will seek funding and partnership opportunities to accomplish roost site monitoring and will adapt the management plan to incorporate more specific protection and avoidance measures for the bat at identified roost sites on the installation (Air Force 2016, appendix G). When compatible with mission requirements, the Base will also promote the use of environmentally friendly lighting practices to minimize impacts to the bat (Air Force 2016, appendix G). The full suite of protective measures incorporated in the Base's INRMP is expected to benefit the species and its habitat.

Based on the above considerations, and in accordance with section 4(a)(3)(B)(i) of the Act, we have determined that the identified lands are subject to Avon Park Air Force Range's and the Base's INRMPs and that conservation efforts identified in the INRMPs will provide a benefit to the Florida bonneted bat. Therefore, lands within these installations are exempt from critical habitat designation under section 4(a)(3) of the Act. Accordingly, we are not including approximately 99,803 ac (40,389 ha) of habitat in this proposed critical habitat designation because of these exemptions.

Consideration of Impacts Under Section 4(b)(2) of the Act

Section 4(b)(2) of the Act states that the Secretary shall designate and make revisions to critical habitat on the basis of the best available scientific data after taking into consideration the economic impact, national security impact, and any other relevant impact of specifying any particular area as critical habitat. The Secretary may exclude an area from critical habitat if we determine that the benefits of such exclusion outweigh the benefits of specifying such area as part of the critical habitat, unless we determine, based on the best scientific data available, that the failure to designate such area as critical habitat will result in the extinction of the species. In making the determination to exclude a particular area, the statute on its face, as well as the legislative history, are clear that the Secretary has broad discretion regarding which factor(s) to use and how much weight to give to any factor.

Under section 4(b)(2) of the Act, we may exclude an area from designated critical habitat based on economic impacts, impacts on national security, or any other relevant impacts. In considering whether to exclude a particular area from the designation, we identify the benefits of including the area in the designation, identify the benefits of excluding the area from the designation, and evaluate whether the

benefits of exclusion outweigh the benefits of inclusion. If the analysis indicates that the benefits of exclusion outweigh the benefits of inclusion, the Secretary may exercise discretion to exclude the area only if such exclusion would not result in the extinction of the species. We describe below our process for considering each category of impacts and our analyses of the relevant impacts.

Exclusion Requests Received During the Previous Public Comment Period

During the public comment period for the June 10, 2020, proposed critical habitat designation (85 FR 35510), we received nine requests for exclusion from critical habitat designation. Of these, two requests do not overlap with this revised proposed designation, while the remaining seven requests overlap to some degree (see table 2, below). Additionally, requests for exclusion of federal lands are not included in table 2, given the high standard set in our 2016 policy regarding exclusions of Federal lands under 4(b)(2) of the Act (2016 Policy). As part of our final rule, we may evaluate the areas in Table 2 for possible exclusion from the final critical habitat designation. All requests received as public comments are available for review at <https://www.regulations.gov> under Docket No. FWS-R4-ES-2019-0106.

TABLE 2—EXCLUSION REQUESTS RECEIVED DURING THE 2020 PUBLIC COMMENT PERIOD ON THE PROPOSED CRITICAL HABITAT DESIGNATION FOR THE FLORIDA BONNETED BAT AND CORRESPONDING OVERLAP WITH REVISED PROPOSED CRITICAL HABITAT UNITS IN THIS RULE

Requesting party (Public comment No. on https://www.regulations.gov)	Area requested for exclusion	Basis for exclusion per requesting party	Overlap with revised proposed critical habitat	
			Unit/subunit	Acres
Aliese Priddy, JB Ranch I, LLC (FWS-R4-ES-2019-0106-0464 and attachment).	Property owned by JB Ranch I, LLC, and Sunniland Family Limited Partnership.	Economic, No ecological benefit.	No overlap	N/A.
Miami-Dade Limestone Products Association (FWS-R4-ES-2019-0106-0386 and attachment).	Lands overlapping the Florida legislature-designated Lake Belt mining area.	No ecological benefit.	No overlap	N/A.
Florida Power & Light (FPL) (FWS-R4-ES-2019-0106-0449 and attachment).	All FPL electric utility sub-stations ¹ and rights-of-way containing aboveground linear facilities.	Conservation plans or programs, Economic.	All	Insufficient information to determine or estimate.
Micosukee Tribe of Florida (Comment submitted directly to the Service).	Tribal reservation lands and fee lands ..	Tribal lands, Conservation plans or programs.	1	1.25.
U.S. Army Corps of Engineers (Comment submitted directly to the Service).	Lands enrolled in the Wetland Reserve Easement Partnership Program (formerly called Wetland Reserve Program).	Economic	2A	387.
	Lands within the Picayune Strand Restoration Project.	Economic	6	64,490.
Seminole Tribe of Florida (FWS-R4-ES-2019-0106-0380 and attachment).	Tribal reservation lands and fee lands ..	Tribal lands, Conservation plans or programs.	6	14,455.
Collier Enterprises Management, Inc. (FWS-R4-ES-2019-0106-0461 and attachment).	Lands within the boundary of the draft East Collier Multiple Species Habitat Conservation Plan.	Conservation plans or programs.	5	Included ² : 2,013. Eligible ³ : 163.

TABLE 2—EXCLUSION REQUESTS RECEIVED DURING THE 2020 PUBLIC COMMENT PERIOD ON THE PROPOSED CRITICAL HABITAT DESIGNATION FOR THE FLORIDA BONNETED BAT AND CORRESPONDING OVERLAP WITH REVISED PROPOSED CRITICAL HABITAT UNITS IN THIS RULE—Continued

Requesting party (Public comment No. on https://www.regulations.gov)	Area requested for exclusion	Basis for exclusion per requesting party	Overlap with revised proposed critical habitat	
			Unit/subunit	Acres
Collier Mosquito Control District (MCD) (FWS-R4-ES-2019-0106-0385 and attachment).	Lands within the existing and proposed Collier MCD boundaries.	Economic	6	Included ² : 1,561.
			5	Eligible ³ : 35.
			6	Existing MCD: 317. Proposed MCD: 3,118. Existing MCD: 166. Proposed MCD: 78,568.

¹ As developed areas, electric utility substations were excluded by text in the June 10, 2020, proposed critical habitat rule (85 FR 35510), and remain excluded by text in this revised proposed rule.

² “Included” lands are areas covered by draft HCP; certain impacts/development actions are allowed.

³ “Eligible” lands are not included in draft HCP but are eligible to join without amending the HCP.

Consideration of Economic Impacts

Section 4(b)(2) of the Act and its implementing regulations require that we consider the economic impact that may result from a designation of critical habitat. For information on how probable economic impacts of a designation were assessed, please see the *Exclusions Based on Economic Impacts* section in the proposed critical habitat rule (85 FR 35510, June 10, 2020). For this particular revised proposed designation, we revised the incremental effects memorandum (IEM) to consider the probable incremental economic impacts that may result from this designation of critical habitat. The information contained in our revised IEM was then used to develop a screening analysis of the probable effects of the designation of critical habitat for the Florida bonneted bat. This screening analysis combined with the information contained in our IEM constitute what we consider to be our draft economic analysis (DEA) of the revised proposed critical habitat designation for the Florida bonneted bat; our DEA is summarized in the narrative below.

Executive Orders (E.O.s) 12866 and 13563 direct Federal agencies to assess the costs and benefits of available regulatory alternatives in quantitative (to the extent feasible) and qualitative terms. Consistent with the E.O. regulatory analysis requirements, our effects analysis under the Act may take into consideration impacts to both directly and indirectly affected entities, where practicable and reasonable. If sufficient data are available, we assess to the extent practicable the probable impacts to both directly and indirectly affected entities. As part of our screening analysis, we considered the types of economic activities that are

likely to occur within the areas likely affected by the critical habitat designation. In our evaluation of the probable incremental economic impacts that may result from this revised proposed designation of critical habitat for the Florida bonneted bat, first we identified, in the revised IEM dated June 22, 2021, probable incremental economic impacts associated with the following categories of activities: (1) Commercial or residential development; (2) transportation; (3) utilities; (4) energy (including solar, wind, and oil and gas); (5) water management (including water supply, flood control, and water quality); (6) recreation; (7) land management (including prescribed burning and invasive species control); and (8) habitat and hydrologic restoration. We considered each industry or category individually. Additionally, we considered whether their activities have any Federal involvement. Critical habitat designation generally will not affect activities that do not have any Federal involvement; under the Act, designation of critical habitat only affects activities conducted, funded, permitted, or authorized by Federal agencies. Because the Florida bonneted bat is already listed under the Act, in areas where the species is present, Federal agencies are currently required to consult with the Service under section 7 of the Act on activities they fund, permit, or implement that may affect the species. If we finalize this revised proposed critical habitat designation, our consultation would include an evaluation of measures to avoid the destruction or adverse modification of critical habitat.

In our IEM, we attempted to clarify the distinction between the effects that result from the species being listed and

those attributable to the critical habitat designation (*i.e.*, difference between the jeopardy and adverse modification standards) for the Florida bonneted bat's critical habitat. The following specific circumstances in this case help to inform our evaluation: (1) The essential physical or biological features identified for critical habitat are the same features essential for the life requisites of the species, and (2) any actions that would result in sufficient harm to constitute jeopardy to the Florida bonneted bat would also likely adversely affect the essential physical or biological features of critical habitat. The IEM outlines our rationale concerning this limited distinction between baseline conservation efforts and incremental impacts of the designation of critical habitat for this species. This evaluation of the incremental effects has been used as the basis to evaluate the probable incremental economic impacts of this revised proposed designation of critical habitat.

The revised proposed critical habitat designation for the Florida bonneted bat consists of nine units, all occupied by the species, totaling 1,174,011 ac (475,105 ha) and including lands under Federal, Tribal, State, county, local, and private jurisdictions (see table 1, above). Because all areas are occupied, the economic impacts of implementing the rule through section 7 of the Act will most likely be limited to additional administrative effort to consider adverse modification. This finding is based on the following factors:

- Any activities with a Federal nexus occurring within occupied habitat will be subject to section 7 consultation requirements regardless of critical habitat designation, due to the presence of the listed species; and

- In most cases, project modifications requested to avoid adverse modification are likely to be the same as those needed to avoid jeopardy in occupied habitat.

Our analysis considers the potential need to consult on development, transportation, utilities, land management, habitat restoration, and other activities authorized, undertaken, or funded by Federal agencies within critical habitat. The total incremental section 7 costs associated with the designation of the proposed units are estimated to be less than \$70,800 per year, with the highest costs expected in Unit 6 (IEc 2021, pp. 2, 25). While the revised proposed critical habitat area is relatively large, incremental section 7 costs are kept comparatively low due to the strong baseline protections that already exist for this species due to its listed status, the existence of a consultation area map that alerts managing agencies about the location of the species and its habitat, and the presence of other listed species in the area.

We are soliciting data and comments from the public on the DEA discussed above, as well as on all aspects of this revised proposed rule and our required determinations. During the development of a final designation, we will consider the information presented in the DEA and any additional information on economic impacts we receive during the public comment period to determine whether any specific areas should be excluded from the final critical habitat designation under authority of section 4(b)(2) and our implementing regulations at 50 CFR 17.90. If we receive credible information regarding the existence of a meaningful economic or other relevant impact supporting a benefit of exclusion, we will conduct an exclusion analysis for the relevant area or areas. We may also exercise the discretion to evaluate any other particular areas for possible exclusion. Furthermore, when we conduct an exclusion analysis based on impacts identified by experts in, or sources with firsthand knowledge about, impacts that are outside the scope of the Service's expertise, we will give weight to those impacts consistent with the expert or firsthand information unless we have rebutting information. We may exclude an area from critical habitat if we determine that the benefits of excluding the area outweigh the benefits of including the area, provided the exclusion will not result in the extinction of this species.

Consideration of National Security Impacts

For information on how probable impacts to national security were assessed, please see the Impacts on National Security and Homeland Security section in the proposed critical habitat rule (85 FR 35510, June 10, 2020). We have evaluated whether any of the lands within this revised proposed designation of critical habitat are owned by DoD or DHS or could lead to national-security or homeland-security impacts if designated. In this discussion, we describe the areas within the revised proposed designation that are owned by DoD or DHS or for which designation could lead to national-security or homeland-security impacts. For each area, we describe the available information indicating whether we have reason to consider excluding the area from the designation. If, during the comment period, we identify or receive credible information about additional areas for which designation may result in incremental national-security or homeland-security impacts, then we will also conduct a discretionary exclusion analysis to determine whether to exclude those additional areas under the authority of section 4(b)(2) of the Act and our implementing regulations at 50 CFR 17.90.

Department of Homeland Security

We have determined that some lands within Unit 9, Subunit O, of the revised proposed critical habitat designation for the Florida bonneted bat are owned, managed, or used by the U.S. Coast Guard (USCG), which is part of the DHS.

The USCG property is separated into two main areas: the Communications Station Miami and the Civil Engineering Unit (CEU). The Communications Station houses transmitting and receiving antennas. The CEU plans and executes projects at regional shore facilities, such as construction and post-disaster assessments.

The USCG parcel contains approximately 100 ac (40 ha) of standing pine rocklands. The remainder of the site, outside of the developed areas, is made up of scraped pine rocklands that are mowed three to four times per year for maintenance of a communications antenna field. Although disturbed, this scraped area maintains sand substrate and many native pine rockland species; the Florida bonneted bat has also been documented on adjacent property. The USCG parcel has a 2017 Natural Resources Management Plan (Gottfried 2017, entire) that includes habitat

management and restoration recommendations for their Pineland Natural Area, a 72-ac (29-ha) conservation area within this property. Recommended management includes prescribed fire, control of invasive plants, and protection of lands from further development or degradation. In addition, the standing pine rockland area is partially managed through an active recovery grant to the Institute for Regional Conservation. Under this grant, up to 39 ac (16 ha) of standing pine rocklands will undergo invasive vegetation control.

Based on a review of the specific mission of the USCG facility in conjunction with the measures and efforts set forth in the management plan to preserve pine rockland habitat and protect sensitive and listed species, we have determined that it is unlikely that the critical habitat, if finalized as proposed in this document, would negatively impact the facility or its operations. As a result, we do not anticipate any impact on national security. Consequently, the Secretary does not intend to exercise her discretion to exclude any of these areas from the final designation based on impacts on national security. We will, however, review this determination, in light of any new information and public comments we receive prior to making a decision in the final rule.

Department of Defense

We have determined that the U.S. Army Corps of Engineers, a branch of the DoD, retains ownership over a 14-ac (6-ha)-parcel within Unit 9, Subunit O, of the revised proposed critical habitat designation for the Florida bonneted bat. This area is a combination of standing and scraped pine rocklands but is not managed for preservation of natural resources. The U.S. Army Corps of Engineers does not have any specific management plan for the Florida bonneted bat or its habitat covering these lands. Activities conducted on this site are unknown, but we do not anticipate any impact on national security. Consequently, the Secretary does not intend to exercise her discretion to exclude any of these areas from the final designation based on impacts on national security. We will, however, review this determination, in light of any new information and public comments we receive, prior to making a decision in the final rule.

Consideration of Other Relevant Impacts

Under section 4(b)(2) of the Act, we consider any other relevant impacts, in addition to economic impacts and

impacts on national security discussed above. Other relevant impacts may include, but are not limited to, impacts to Tribes, States, local governments, public health and safety, community interests, the environment (such as increased risk of wildfire), Federal lands, and conservation plans, agreements, or partnerships. To identify other relevant impacts that may affect the exclusion analysis, we consider a number of factors, including whether there are permitted conservation plans covering the species in the area—such as HCPs, safe harbor agreements (SHAs), or candidate conservation agreements with assurances (CCAAs)—or whether there are non-permitted conservation agreements and partnerships that may be impaired by designation of, or exclusion from, critical habitat. In addition, we look at whether Tribal conservation plans or partnerships, Tribal resources, or government-to-government relationships of the United States with Tribal entities may be affected by the designation. We also consider any State, local, public-health, community-interest, environmental, or social impacts that might occur because of the designation.

When analyzing other relevant impacts of including a particular area in a designation of critical habitat, we weigh those impacts relative to the conservation value of the particular area. To determine the conservation value of designating a particular area, we consider a number of factors, including, but not limited to, the additional regulatory benefits that the area would receive due to the protection from destruction or adverse modification as a result of actions with a Federal nexus, the educational benefits of mapping essential habitat for recovery of the listed species, and any benefits that may result from a designation due to State or Federal laws that may apply to critical habitat.

In the case of the Florida bonneted bat, the benefits of critical habitat include public awareness of the presence of the species and the importance of habitat protection and, where a Federal nexus exists, increased habitat protection for Florida bonneted bat due to protection from destruction or adverse modification of critical habitat. Continued implementation of an ongoing management plan that provides conservation equal to or more than the protections that result from a critical habitat designation would reduce those benefits of including that specific area in the critical habitat designation.

We evaluate the existence of a conservation plan when considering the

benefits of inclusion. We consider a variety of factors, including, but not limited to, whether the plan is finalized; how it provides for the conservation of the essential physical or biological features; whether there is a reasonable expectation that the conservation management strategies and actions contained in a management plan will be implemented into the future; whether the conservation strategies in the plan are likely to be effective; and whether the plan contains a monitoring program or adaptive management to ensure that the conservation measures are effective and can be adapted in the future in response to new information.

After identifying the benefits of inclusion and the benefits of exclusion, we carefully weigh the two sides to evaluate whether the benefits of exclusion outweigh those of inclusion. If our analysis indicates that the benefits of exclusion outweigh the benefits of inclusion, we then determine whether exclusion would result in extinction of the species. If failure to designate an area as critical habitat will result in extinction, we will not exclude it from the designation.

Private or Other Non-Federal Conservation Plans Related to Permits Under Section 10 of the Act

HCPs for incidental take permits under section 10(a)(1)(B) of the Act provide for partnerships with non-Federal entities to minimize and mitigate impacts to listed species and their habitat. In some cases, HCP permittees agree to do more for the conservation of the species and their habitats on private lands than designation of critical habitat would provide alone. We place great value on the partnerships that are developed during the preparation and implementation of HCPs.

CCAAs and SHAs are voluntary agreements designed to conserve candidate and listed species, respectively, on non-Federal lands. In exchange for actions that contribute to the conservation of species on non-Federal lands, participating property owners are covered by an “enhancement of survival” permit under section 10(a)(1)(A) of the Act, which authorizes incidental take of the covered species that may result from implementation of conservation actions or specific land uses. In the case of SHAs, the permit would allow participants to take listed species or modify habitat to return population levels and habitat conditions to those agreed upon as baseline condition under the agreements. The Service also provides enrollees assurances that we will not impose

further land-, water-, or resource-use restrictions, or require additional commitments of land, water, or finances, beyond those agreed to in the agreements.

When we undertake a discretionary section 4(b)(2) exclusion analysis based on permitted conservation plans such as CCAAs, SHAs, and HCPs, we consider the following three factors:

- (i) Whether the permittee is properly implementing the conservation plan or agreement;
- (ii) Whether the species for which critical habitat is being designated is a covered species in the conservation plan or agreement; and
- (iii) Whether the conservation plan or agreement specifically addresses the habitat of the species for which critical habitat is being designated and meets the conservation needs of the species in the planning area.

The revised proposed critical habitat designation includes areas that are covered by the Coral Reef Commons HCP, a permitted plan providing for the conservation of the Florida bonneted bat.

Coral Reef Commons HCP

The revised proposed designation includes the Coral Reef Commons mixed-use community, which consists of 900 apartments, retail stores, restaurants, and parking. In 2017, an HCP and associated permit under section 10 of the Act was developed and issued for the Coral Reef Commons development (Church Environmental 2017, entire). As part of the HCP and permit, an approximately 52-ac (21-ha) on-site preserve was established under a conservation encumbrance that will be managed in perpetuity for pine rockland habitat and sensitive and listed species, including the Florida bonneted bat. Also, an additional approximately 52-ac (21-ha) off-site mitigation area was set aside for Coral Reef Commons. Both the on-site preserves and the off-site mitigation area will be managed to maintain healthy pine rockland habitat through the use of invasive, exotic plant management, mechanical treatment, and prescribed fire. Since initiating the Coral Reef Commons HCP, pine rockland restoration efforts have been conducted within all the management units in the on-site preserve and the off-site mitigation area. A second round of prescribed fire began in February 2021. Currently, the on-site preserve meets or exceeds the success criteria described in the HCP.

Maintenance of pine rockland habitat specifically relates to conservation of ecological diversity described in physical or biological feature 4, and

other biological objectives of the HCP (e.g., implementation of a burn plan, minimizing pesticide use to the extent practicable) may provide conservation benefits related to physical or biological features 1, 2, and 3.

After considering the factors described above, we have identified the 104 ac (42 ha) under the Coral Reef Commons HCP (in Unit 9, Subunit O) as an area we have reason to consider excluding because of its permitted plan. Specifically, our reasons for considering this area for potential exclusion are not only that the Florida bonneted bat is a covered species within the HCP; but also that the HCP specifically addresses conservation of pine rockland habitat, generally addresses four of the physical or biological features essential for the conservation of the species, and may meet the conservation needs of the species within the area covered by the HCP. We will more thoroughly review the HCP, its implementation of the conservation measures for the Florida bonneted bat and its habitat therein, and public comment on this issue prior to finalizing critical habitat, and if appropriate, exclude from critical habitat for the Florida bonneted bat those lands associated with the Coral Reef Commons HCP that are in the preserve and offsite mitigation area.

Tribal Lands

Several Executive Orders, Secretarial Orders, and policies concern working with Tribes. These guidance documents generally confirm our trust responsibilities to Tribes, recognize that Tribes have sovereign authority to control Tribal lands, emphasize the importance of developing partnerships with Tribal governments, and direct the Service to consult with Tribes on a government-to-government basis.

A joint Secretarial Order that applies to both the Service and the National Marine Fisheries Service (NMFS)—Secretarial Order 3206, *American Indian Tribal Rights, Federal–Tribal Trust Responsibilities, and the Endangered Species Act* (June 5, 1997) (S.O. 3206)—is the most comprehensive of the various guidance documents related to Tribal relationships and Act implementation, and it provides the most detail directly relevant to the designation of critical habitat. In addition to the general direction discussed above, the appendix to S.O. 3206 explicitly recognizes the right of Tribes to participate fully in any listing process that may affect Tribal rights or Tribal trust resources; this includes the designation of critical habitat. Section 3(b)(4) of the appendix requires the

Service to consult with affected Tribes “when considering the designation of critical habitat in an area that may impact Tribal trust resources, Tribally-owned fee lands, or the exercise of Tribal rights.” That provision also instructs the Service to avoid including Tribal lands within a critical habitat designation unless the area is essential to conserve a listed species, and it requires the Service to “evaluate and document the extent to which the conservation needs of the listed species can be achieved by limiting the designation to other lands.”

Our implementing regulations at 50 CFR 17.90(d)(1)(i) are consistent with S.O. 3206. When we undertake a discretionary exclusion analysis, in accordance with S.O. 3206 we consult with any Tribe whose Tribal trust resources, Tribally owned fee lands, or Tribal rights may be affected by including any particular areas in the designation, and we evaluate the extent to which the conservation needs of the species can be achieved by limiting the designation to other areas. We then weighed nonbiological impacts to Tribal lands and resources consistent with the information provided by the Tribes.

However, S.O. 3206 does not override the Act’s statutory requirement of designation of critical habitat. As stated above, we must consult with any Tribe when a designation of critical habitat may affect Tribal lands or resources. The Act requires us to identify areas that meet the definition of “critical habitat” (i.e., areas occupied at the time of listing that contain the essential physical or biological features that may require special management or protection and unoccupied areas that are essential to the conservation of a species), without regard to land ownership. While S.O. 3206 provides important direction, it expressly states that it does not modify the Secretary’s statutory authority under the Act or other statutes.

The revised proposed critical habitat designation includes the following Tribal lands or resources:

Seminole Tribe of Florida: The revised proposed designation includes an area (14,455 ac (5,850 ha)) within Unit 6 (Big Cypress) that overlaps with Seminole Tribe of Florida Trust lands. The Seminole Tribe Wildlife Conservation Plan, Fire Management Plan, and Forest Management Plan cover these lands for the protection of listed and endangered species, including the Florida bonneted bat. The Service reviewed these plans and issued a biological opinion on December 19, 2014, which we amended on June 9,

2017 (see Supporting Documents). The Wildlife Conservation Plan includes conservation measures in place that support the Florida bonneted bat and its habitat (e.g., limit impacts to potential roost trees during prescribed burns and home site/access road construction, maintain bonneted bat habitat through prescribed burning and construction of bat houses). The conservation measures specifically address conservation of roosting and foraging habitat (i.e., physical or biological features 1 through 4), and maintenance of that habitat through active management; therefore, the measures appear to meet the conservation needs of the Florida bonneted bat within the area covered by the plan. As such, we are considering 14,455 ac (5,850 ha) of Seminole Tribe of Florida Trust lands within Unit 6 (Big Cypress) for exclusion.

Miccosukee Tribe of Florida: The revised proposed designation includes an area (1.25 ac (0.5 ha)) within Unit 1 (Kissimmee) that overlaps with Miccosukee Tribe of Florida fee lands. At present, we do not have any information on how this small parcel is managed, but we are considering 1.25 ac (0.5 ha) of Miccosukee Tribe of Florida fee lands within Unit 1 (Kissimmee) for exclusion.

Summary of Exclusions Considered Under 4(b)(2) of the Act

Based on the information provided by entities seeking exclusion, as well as any additional public comments we receive, we will evaluate whether certain lands in the revised proposed critical habitat units are appropriate for exclusion from the final designation under section 4(b)(2) of the Act. If the analysis indicates that the benefits of excluding lands from the final designation outweigh the benefits of designating those lands as critical habitat, then the Secretary may exercise her discretion to exclude the lands from the final designation.

Table 3, below, provides approximate areas of lands that meet the definition of critical habitat but for which we are considering possible exclusion under section 4(b)(2) of the Act from the final critical habitat designation for the Florida bonneted bat. In addition, we may consider previously requested exclusion requests received during the public comment period on the June 10, 2020, proposed rule that overlap with revised proposed critical habitat (see table 2, above).

TABLE 3—AREAS CONSIDERED FOR EXCLUSION WITHIN REVISED PROPOSED CRITICAL HABITAT UNITS IN ACCORDANCE WITH THE 2016 POLICY

Unit	Specific area	Areas meeting the definition of critical habitat, in acres (hectares)	Areas considered for possible exclusion, in acres (hectares)	Rationale for proposed exclusion
Unit 1: Kissimmee	Miccosukee Tribe of Florida.	1.25 (0.5)	1.25 (0.5)	Tribal fee lands.
Unit 6: Big Cypress	Seminole Tribe of Florida.	14,455 (5,850)	14,455 (5,850)	Tribal Trust lands; under natural resource management plans.
Unit 9: Miami Rocklands	Coral Reef Commons	104 (42)	104 (42)	Lands under HCP specifically addressing the species.

In conclusion, for this revised proposed rule, we have reason to consider excluding the areas identified above based on other relevant impacts. We specifically solicit comments on the inclusion or exclusion of such areas. During the development of a final designation, we will consider any information currently available or received during the public comment period regarding other relevant impacts of this revised proposed designation and will determine whether these or any other specific areas should be excluded from the final critical habitat designation under the authority of section 4(b)(2) of the Act and our implementing regulations at 50 CFR 17.90.

Required Determinations

Clarity of the Rule

We are required by Executive Orders 12866 and 12988 and by the Presidential Memorandum of June 1, 1998, to write all rules in plain language. This means that each rule we publish must:

- (1) Be logically organized;
- (2) Use the active voice to address readers directly;
- (3) Use clear language rather than jargon;
- (4) Be divided into short sections and sentences; and
- (5) Use lists and tables wherever possible.

If you feel that we have not met these requirements, send us comments by one of the methods listed in **ADDRESSES**. To better help us revise the rule, your comments should be as specific as possible. For example, you should tell us the numbers of the sections or paragraphs that are unclearly written, which sections or sentences are too long, the sections where you feel lists or tables would be useful, etc.

Regulatory Planning and Review (Executive Orders 12866 and 13563)

Executive Order 12866 provides that the Office of Information and Regulatory

Affairs (OIRA) in the Office of Management and Budget will review all significant rules. OIRA has determined that this rule is not significant.

Executive Order 13563 reaffirms the principles of E.O. 12866 while calling for improvements in the nation's regulatory system to promote predictability, to reduce uncertainty, and to use the best, most innovative, and least burdensome tools for achieving regulatory ends. The Executive order directs agencies to consider regulatory approaches that reduce burdens and maintain flexibility and freedom of choice for the public where these approaches are relevant, feasible, and consistent with regulatory objectives. E.O. 13563 emphasizes further that regulations must be based on the best available science and that the rulemaking process must allow for public participation and an open exchange of ideas. We have developed this proposed rule in a manner consistent with these requirements.

Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*)

Under the Regulatory Flexibility Act (RFA; 5 U.S.C. 601 *et seq.*), as amended by the Small Business Regulatory Enforcement Fairness Act of 1996 (SBREFA; 5 U.S.C. 801 *et seq.*), whenever an agency is required to publish a notice of rulemaking for any proposed or final rule, it must prepare and make available for public comment a regulatory flexibility analysis that describes the effects of the rule on small entities (*i.e.*, small businesses, small organizations, and small government jurisdictions). However, no regulatory flexibility analysis is required if the head of the agency certifies the rule will not have a significant economic impact on a substantial number of small entities. The SBREFA amended the RFA to require Federal agencies to provide a certification statement of the factual basis for certifying that the rule will not have a significant economic impact on a substantial number of small entities.

According to the Small Business Administration, small entities include small organizations such as independent nonprofit organizations; small governmental jurisdictions, including school boards and city and town governments that serve fewer than 50,000 residents; and small businesses (13 CFR 121.201). Small businesses include manufacturing and mining concerns with fewer than 500 employees, wholesale trade entities with fewer than 100 employees, retail and service businesses with less than \$5 million in annual sales, general and heavy construction businesses with less than \$27.5 million in annual business, special trade contractors doing less than \$11.5 million in annual business, and agricultural businesses with annual sales less than \$750,000. To determine whether potential economic impacts to these small entities are significant, we considered the types of activities that might trigger regulatory impacts under this designation as well as types of project modifications that may result. In general, the term "significant economic impact" is meant to apply to a typical small business firm's business operations.

Under the RFA, as amended, and as understood in light of recent court decisions, Federal agencies are required to evaluate the potential incremental impacts of rulemaking on those entities directly regulated by the rulemaking itself; in other words, the RFA does not require agencies to evaluate the potential impacts to indirectly regulated entities. The regulatory mechanism through which critical habitat protections are realized is section 7 of the Act, which requires Federal agencies, in consultation with the Service, to ensure that any action authorized, funded, or carried out by the agency is not likely to destroy or adversely modify critical habitat. Therefore, under section 7, only Federal action agencies are directly subject to the specific regulatory requirement

(avoiding destruction and adverse modification) imposed by critical habitat designation. Consequently, it is our position that only Federal action agencies would be directly regulated if we adopt this revised proposed critical habitat designation. The RFA does not require evaluation of the potential impacts to entities not directly regulated. Moreover, Federal agencies are not small entities. Therefore, because no small entities would be directly regulated by this rulemaking, the Service certifies that, if made final as proposed in this document, the revised proposed critical habitat designation will not have a significant economic impact on a substantial number of small entities.

In summary, we have considered whether this revised proposed designation would result in a significant economic impact on a substantial number of small entities. For the above reasons and based on currently available information, we certify that, if made final, this revised proposed critical habitat designation would not have a significant economic impact on a substantial number of small business entities. Therefore, an initial regulatory flexibility analysis is not required.

Energy Supply, Distribution, or Use—Executive Order 13211

Executive Order 13211 (Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use) requires agencies to prepare Statements of Energy Effects when undertaking certain actions. In our economic analysis, we did not find that this revised proposed critical habitat designation would significantly affect energy supplies, distribution, or use. As most of the area included in this revised proposed critical habitat designation occurs on conservation lands (approximately 89 percent), the likelihood of energy development within critical habitat is low. Therefore, this action is not a significant energy action, and no Statement of Energy Effects is required.

Unfunded Mandates Reform Act (2 U.S.C. 1501 et seq.)

In accordance with the Unfunded Mandates Reform Act (2 U.S.C. 1501 et seq.), we make the following finding:

(1) This proposed rule would not produce a Federal mandate. In general, a Federal mandate is a provision in legislation, statute, or regulation that would impose an enforceable duty upon State, local, or Tribal governments, or the private sector, and includes both “Federal intergovernmental mandates” and “Federal private sector mandates.”

These terms are defined in 2 U.S.C. 658(5)–(7). “Federal intergovernmental mandate” includes a regulation that “would impose an enforceable duty upon State, local, or Tribal governments” with two exceptions. It excludes “a condition of Federal assistance.” It also excludes “a duty arising from participation in a voluntary Federal program,” unless the regulation “relates to a then-existing Federal program under which \$500,000,000 or more is provided annually to State, local, and Tribal governments under entitlement authority,” if the provision would “increase the stringency of conditions of assistance” or “place caps upon, or otherwise decrease, the Federal Government’s responsibility to provide funding,” and the State, local, or Tribal governments “lack authority” to adjust accordingly. At the time of enactment, these entitlement programs were: Medicaid; Aid to Families with Dependent Children work programs; Child Nutrition; Food Stamps; Social Services Block Grants; Vocational Rehabilitation State Grants; Foster Care, Adoption Assistance, and Independent Living; Family Support Welfare Services; and Child Support Enforcement. “Federal private sector mandate” includes a regulation that “would impose an enforceable duty upon the private sector, except (i) a condition of Federal assistance or (ii) a duty arising from participation in a voluntary Federal program.”

The designation of critical habitat does not impose a legally binding duty on non-Federal Government entities or private parties. Under the Act, the only regulatory effect is that Federal agencies must ensure that their actions do not destroy or adversely modify critical habitat under section 7. While non-Federal entities that receive Federal funding, assistance, or permits, or that otherwise require approval or authorization from a Federal agency for an action, may be indirectly impacted by the designation of critical habitat, the legally binding duty to avoid destruction or adverse modification of critical habitat rests squarely on the Federal agency. Furthermore, to the extent that non-Federal entities are indirectly impacted because they receive Federal assistance or participate in a voluntary Federal aid program, the Unfunded Mandates Reform Act would not apply, nor would critical habitat shift the costs of the large entitlement programs listed above onto State governments.

(2) We do not believe that this rule would significantly or uniquely affect small governments because it will not produce a Federal mandate of \$100

million or greater in any year, that is, it is not a “significant regulatory action” under the Unfunded Mandates Reform Act. The designation of critical habitat imposes no obligations on State or local governments and, as such, a Small Government Agency Plan is not required.

Takings—Executive Order 12630

In accordance with E.O. 12630 (Government Actions and Interference with Constitutionally Protected Private Property Rights), we have analyzed the potential takings implications of designating critical habitat for Florida bonneted bat in a takings implications assessment. The Act does not authorize the Service to regulate private actions on private lands or confiscate private property as a result of critical habitat designation. Designation of critical habitat does not affect land ownership, or establish any closures, or restrictions on use of or access to the designated areas. Furthermore, the designation of critical habitat does not affect landowner actions that do not require Federal funding or permits, nor does it preclude development of habitat conservation programs or issuance of incidental take permits to permit actions that do require Federal funding or permits to go forward. However, Federal agencies are prohibited from carrying out, funding, or authorizing actions that would destroy or adversely modify critical habitat. A takings implications assessment has been completed for the revised proposed designation of critical habitat for Florida bonneted bat, and it concludes that, if adopted, this designation of critical habitat does not pose significant takings implications for lands within or affected by the designation.

Federalism—Executive Order 13132

In accordance with E.O. 13132 (Federalism), this proposed rule does not have significant Federalism effects. A federalism summary impact statement is not required. In keeping with Department of the Interior and Department of Commerce policy, we requested information from, and coordinated development of this proposed critical habitat designation with, appropriate State resource agencies. From a federalism perspective, the designation of critical habitat directly affects only the responsibilities of Federal agencies. The Act imposes no other duties with respect to critical habitat, either for States and local governments, or for anyone else. As a result, the proposed rule does not have substantial direct effects either on the States, or on the relationship between

the national government and the States, or on the distribution of powers and responsibilities among the various levels of government. The proposed designation may have some benefit to these governments because the areas that contain the features essential to the conservation of the species are more clearly defined, and the physical or biological features of the habitat necessary for the conservation of the species are specifically identified. This information does not alter where and what federally sponsored activities may occur. However, it may assist State and local governments in long-range planning because they no longer have to wait for case-by-case section 7 consultations to occur.

Where State and local governments require approval or authorization from a Federal agency for actions that may affect critical habitat, consultation under section 7(a)(2) of the Act would be required. While non-Federal entities that receive Federal funding, assistance, or permits, or that otherwise require approval or authorization from a Federal agency for an action, may be indirectly impacted by the designation of critical habitat, the legally binding duty to avoid destruction or adverse modification of critical habitat rests squarely on the Federal agency.

Civil Justice Reform—Executive Order 12988

In accordance with Executive Order 12988 (Civil Justice Reform), the Office of the Solicitor has determined that the rule would not unduly burden the judicial system and that it meets the requirements of sections 3(a) and 3(b)(2) of the Order. We have proposed designating critical habitat in accordance with the provisions of the Act. To assist the public in understanding the habitat needs of the species, this revised proposed rule identifies the physical or biological features essential to the conservation of the species. The proposed areas of critical habitat are presented on maps, and this revised proposed rule provides several options for the interested public to obtain more detailed location information, if desired.

Paperwork Reduction Act of 1995 (44 U.S.C. 3501 et seq.)

This rule does not contain information collection requirements, and a submission to the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 et seq.) is not required. We may not conduct or sponsor and you are not required to respond to a collection of information unless it displays a currently valid OMB control number.

National Environmental Policy Act (42 U.S.C. 4321 et seq.)

It is our position that, outside the jurisdiction of the U.S. Court of Appeals for the Tenth Circuit, we do not need to prepare environmental analyses pursuant to the National Environmental Policy Act (NEPA; 42 U.S.C. 4321 et seq.) in connection with regulations adopted pursuant to section 4(a) of the Act. We published a notice outlining our reasons for this determination in the **Federal Register** on October 25, 1983 (48 FR 49244). This position was upheld by the U.S. Court of Appeals for the Ninth Circuit (*Douglas County v. Babbitt*, 48 F.3d 1495 (9th Cir. 1995), cert. denied 516 U.S. 1042 (1996)).

Government-to-Government Relationship With Tribes

In accordance with the President's memorandum of April 29, 1994 (Government-to-Government Relations with Native American Tribal Governments; 59 FR 22951), Executive Order 13175 (Consultation and Coordination with Indian Tribal Governments), and the Department of the Interior's manual at 512 DM 2, we readily acknowledge our responsibility to communicate meaningfully with recognized Federal Tribes on a government-to-government basis. In accordance with Secretarial Order 3206 of June 5, 1997 (American Indian Tribal Rights, Federal-Tribal Trust Responsibilities, and the Endangered Species Act), we readily acknowledge our responsibilities to work directly with Tribes in developing programs for healthy ecosystems, to acknowledge that Tribal lands are not subject to the same controls as Federal public lands, to remain sensitive to Indian culture, and

to make information available to Tribes. Some areas within the revised proposed designation are included in lands managed by the Seminole Tribe of Florida and Miccosukee Tribe of Indians of Florida (see Units 1 and 6 descriptions; see also *Consideration of Other Relevant Impacts*, above), constituting a total of approximately 14,457 ac (5,851 ha) of Tribal land being proposed as critical habitat. We will continue to work with Tribal entities during the development of a final rule designating critical habitat for the Florida bonneted bat.

References Cited

A complete list of references cited in this rulemaking is available on the internet at <https://www.regulations.gov> and upon request from the Florida Ecological Services Field Office (see **FOR FURTHER INFORMATION CONTACT**).

Authors

The primary authors of this proposed rule are the staff members of the Fish and Wildlife Service's Florida Ecological Services Field Office.

List of Subjects in 50 CFR Part 17

Endangered and threatened species, Exports, Imports, Plants, Reporting and recordkeeping requirements, Transportation, Wildlife.

Proposed Regulation Promulgation

Accordingly, we propose to amend part 17, subchapter B of chapter I, title 50 of the Code of Federal Regulations, as set forth below:

PART 17—ENDANGERED AND THREATENED WILDLIFE AND PLANTS

■ 1. The authority citation for part 17 continues to read as follows:

Authority: 16 U.S.C. 1361–1407; 1531–1544; and 4201–4245, unless otherwise noted.

■ 2. In § 17.11, amend the table in paragraph (h) by revising the entry for “Bat, Florida bonneted” under MAMMALS to read as follows:

§ 17.11 Endangered and threatened wildlife.

*	*	*	*	*
(h)	*	*	*	*

Common name	Scientific name	Where listed	Status	Listing citations and applicable rules
Mammals				
Bat, Florida bonneted	<i>Eumops floridanus</i>	Wherever found	E	78 FR 61004, 10/2/2013; 50 CFR 17.95(a). ^{CH}

Common name	Scientific name	Where listed	Status	Listing citations and applicable rules
*	*	*	*	*

■ 3. In § 17.95, amend paragraph (a) by adding an entry for “Florida Bonneted Bat (*Eumops floridanus*)” before the entry for “Indiana Bat (*Myotis sodalis*)” to read as follows:

§ 17.95 Critical habitat—fish and wildlife.

(a) *Mammals.*

Florida Bonneted Bat (*Eumops floridanus*)

(1) Critical habitat units are depicted for Charlotte, Collier, DeSoto, Glades, Hardee, Hendry, Highlands, Lee, Miami-Dade, Monroe, Okeechobee, Osceola, and Polk Counties, Florida, on the maps in this entry.

(2) Within these areas, the physical or biological features essential to the conservation of Florida bonneted bat consist of the following components:

(i) Habitats that provide for roosting and rearing of offspring. Such habitat provides structural features for rest, digestion of food, social interaction, mating, rearing of young, protection from sunlight and adverse weather conditions, and cover to reduce predation risks for adults and young, and is generally characterized by:

(A) Live or dead trees and tree snags, especially longleaf pine, slash pine, bald cypress, and royal palm, that are on average 57 feet (ft) (17 meters (m)) in height and with an average 15-inch (38-centimeter) diameter at breast height and that are emergent from the surrounding canopy (by an average 16 ft (5 m)); and

(B) Sufficient unobstructed space, with cavities averaging 35 ft (10.7 m) above the ground and roost trees averaging 14 ft (4 m) from the nearest tree, for Florida bonneted bats to emerge from roost trees; this may include open or semi-open canopy and canopy gaps.

(ii) Habitats that provide adequate prey and space for foraging, which may vary widely across the Florida bonneted bat's range, in accordance with ecological conditions, seasons, and

disturbance regimes that influence vegetation structure and prey species' distributions. Foraging habitat may be separate and relatively far from roosting habitat. Essential foraging habitat consists of open areas in or near areas of high insect production or congregation, commonly including, but not limited to:

(A) Freshwater edges, and freshwater herbaceous wetlands (permanent or seasonal);

(B) Prairies;

(C) Wetland and upland shrub; and/or

(D) Wetland and upland forests.

(iii) A dynamic disturbance regime (e.g., fire, hurricanes, forest management) that maintains and regenerates forested habitat, including plant communities, open habitat structure, and temporary gaps, which is conducive to promoting a continual supply of roosting sites, prey items, and suitable foraging conditions.

(iv) A sufficient quantity and diversity of habitats to enable the species to be resilient to short-term impacts associated with disturbance over time (e.g., drought, forest disease). The ecological communities the Florida bonneted bat inhabits differ in hydrology, fire frequency/intensity, climate, prey species, roosting sites, and threats, and include, but are not limited to:

(A) Pine rocklands;

(B) Cypress communities (cypress swamps, strand swamps, domes, sloughs, ponds);

(C) Hydric pine flatwoods (wet flatwoods);

(D) Mesic pine flatwoods; and

(E) High pine.

(v) Habitats that provide structural connectivity where needed to allow for dispersal, gene flow, and natural and adaptive movements, including those that may be necessitated by climate change. These connections may include linear corridors such as vegetated,

riverine, or open-water habitat with opportunities for roosting and/or foraging, or patches (i.e., stepping stones) such as tree islands or other isolated natural areas within a matrix of otherwise low-quality habitat.

(vi) A subtropical climate that provides tolerable conditions for the species such that normal behavior, successful reproduction, and rearing of offspring are possible.

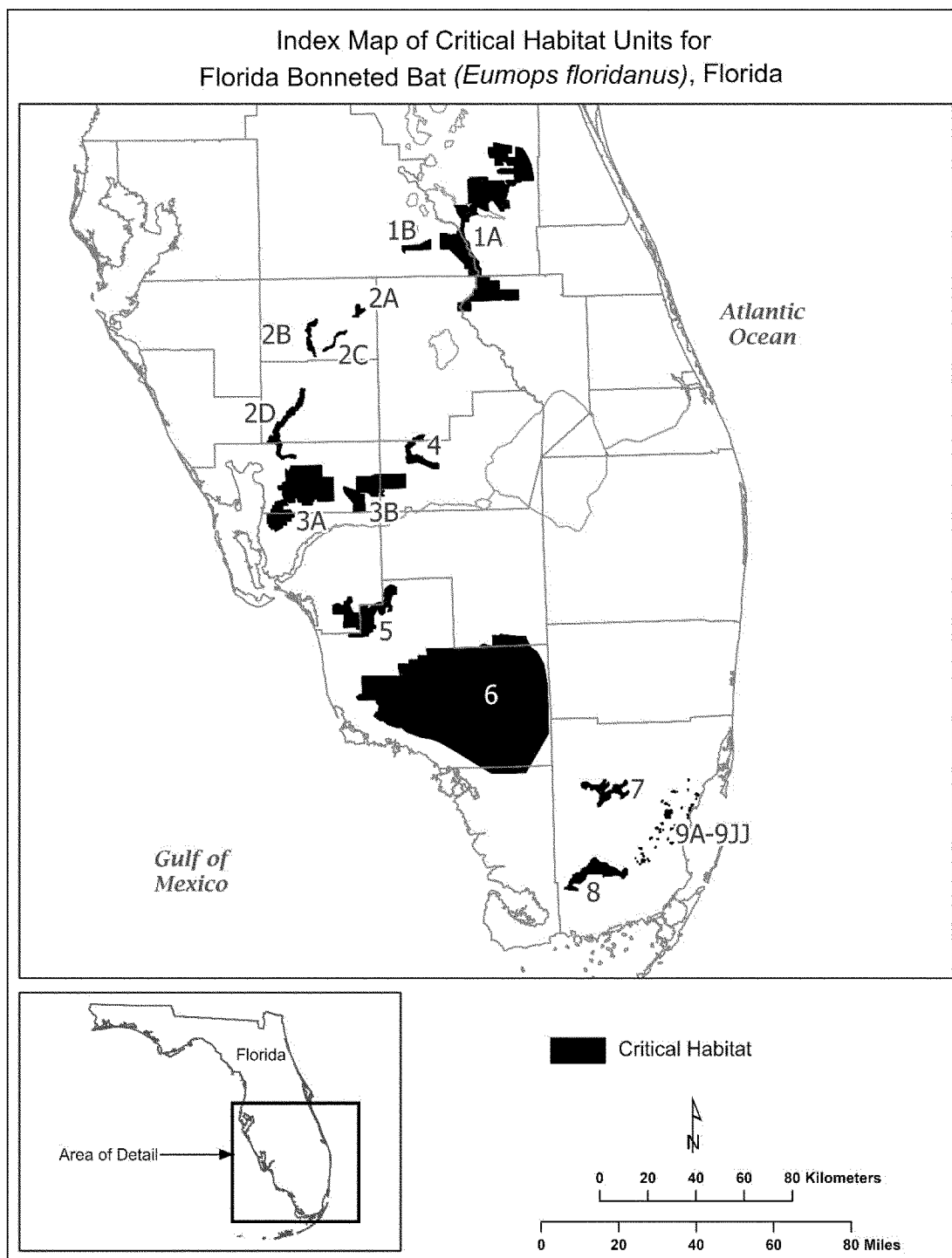
(3) Critical habitat does not include humanmade structures (such as buildings, aqueducts, runways, roads, and other paved areas) and the land on which they are located existing within the legal boundaries on the effective date of the final rule.

(4) Data layers defining map units were created using ESRI ArcGIS mapping software along with various spatial data layers. ArcGIS was also used to calculate the size of habitat areas. The projection used in mapping and calculating distances and locations within the units was World Geodetic System 1984, Universal Transverse Mercator Zone 17 North. The maps in this entry, as modified by any accompanying regulatory text, establish the boundaries of the critical habitat designation. The coordinates or plot points or both on which each map is based are available to the public at <https://www.regulations.gov> at Docket No. FWS-R4-ES-2019-0106, the Florida Ecological Services Field Office website at <https://www.fws.gov/office/florida-ecological-services/library>, and at the field office responsible for this designation. You may obtain field office location information by contacting one of the Service regional offices, the addresses of which are listed at 50 CFR 2.2.

(5) Index map follows:

Figure 1 to Florida Bonneted Bat (*Eumops floridanus*) paragraph (5)

BILLING CODE 4333-15-P



(6) Unit 1: Kissimmee Unit; Polk, Osceola, Highlands, and Okeechobee Counties, Florida.

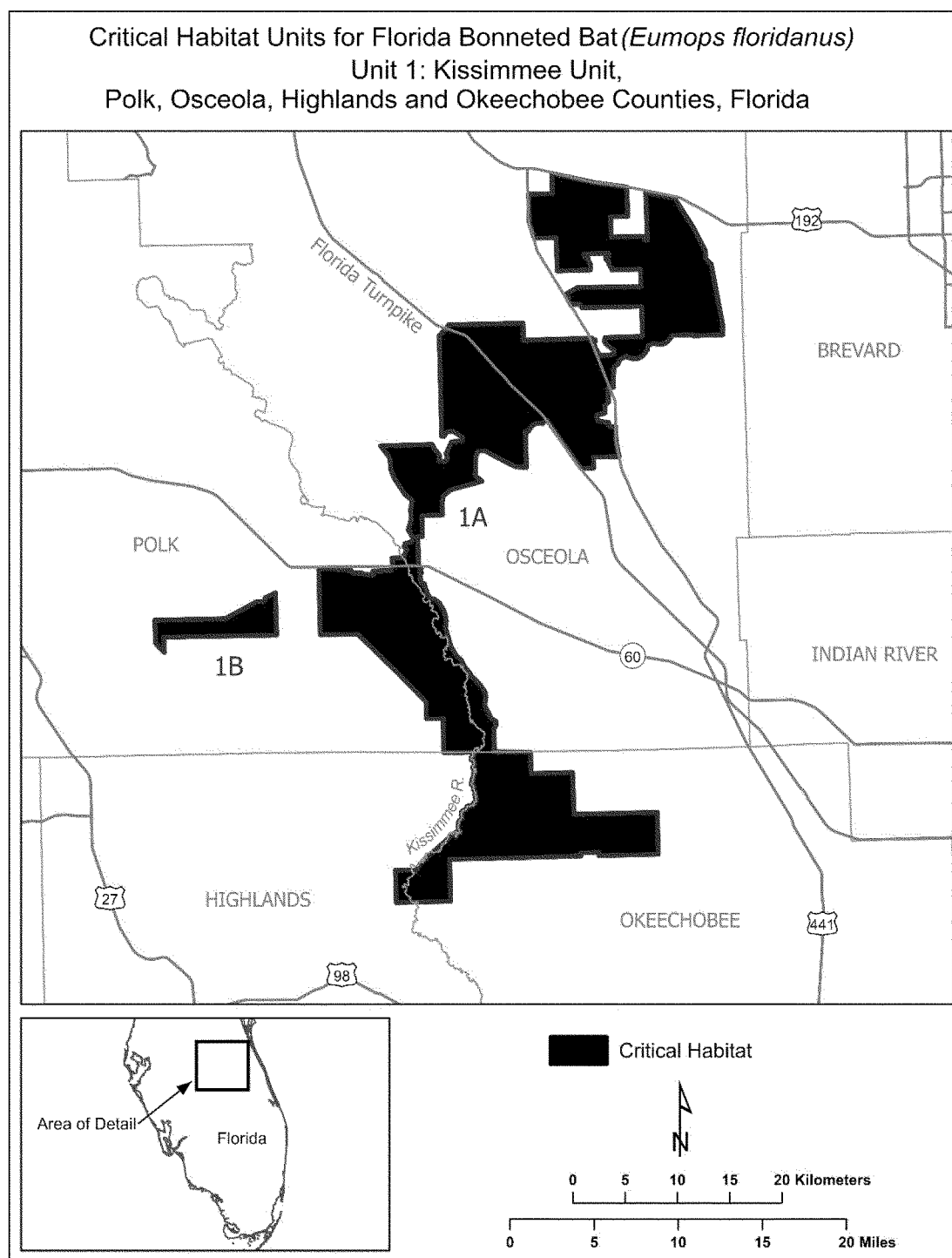
(i) Unit 1 encompasses 175,737 acres (ac) (71,118 hectares (ha)) of lands in

Polk, Osceola, Highlands, and Okeechobee Counties, Florida. This unit consists of two subunits generally located along the eastern bank of Lake Kissimmee northeast to SR-192, north

of SR-60; and along portions of the Kissimmee River, south of SR-60.

(ii) Map of Unit 1 follows:

Figure 2 to Florida Bonneted Bat (*Eumops floridanus*) paragraph (6)(ii)

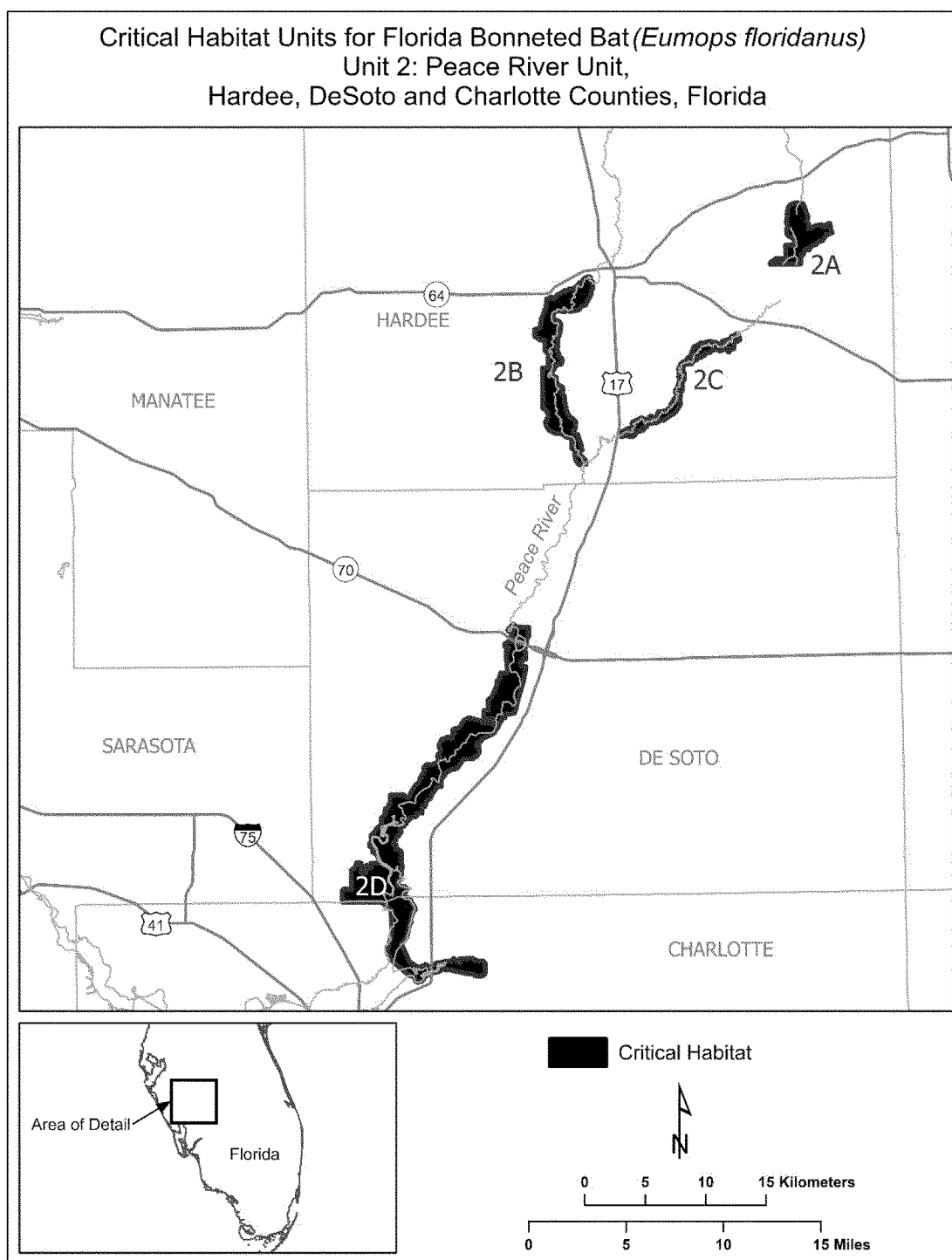


(7) Unit 2: Peace River Unit; Hardee, DeSoto, and Charlotte Counties, Florida.

(i) Unit 2 encompasses 28,046 ac (11,350 ha) of lands in Hardee, DeSoto, and Charlotte Counties, Florida. This

unit consists of four subunits located along portions of the Peace River and its tributaries (e.g., Shell Creek, Charlie Creek), south of CR-64 with the majority west of U.S.-17.

(ii) Map of Unit 2 follows: Figure 3 to Florida Bonneted Bat (*Eumops floridanus*) paragraph (7)(ii)

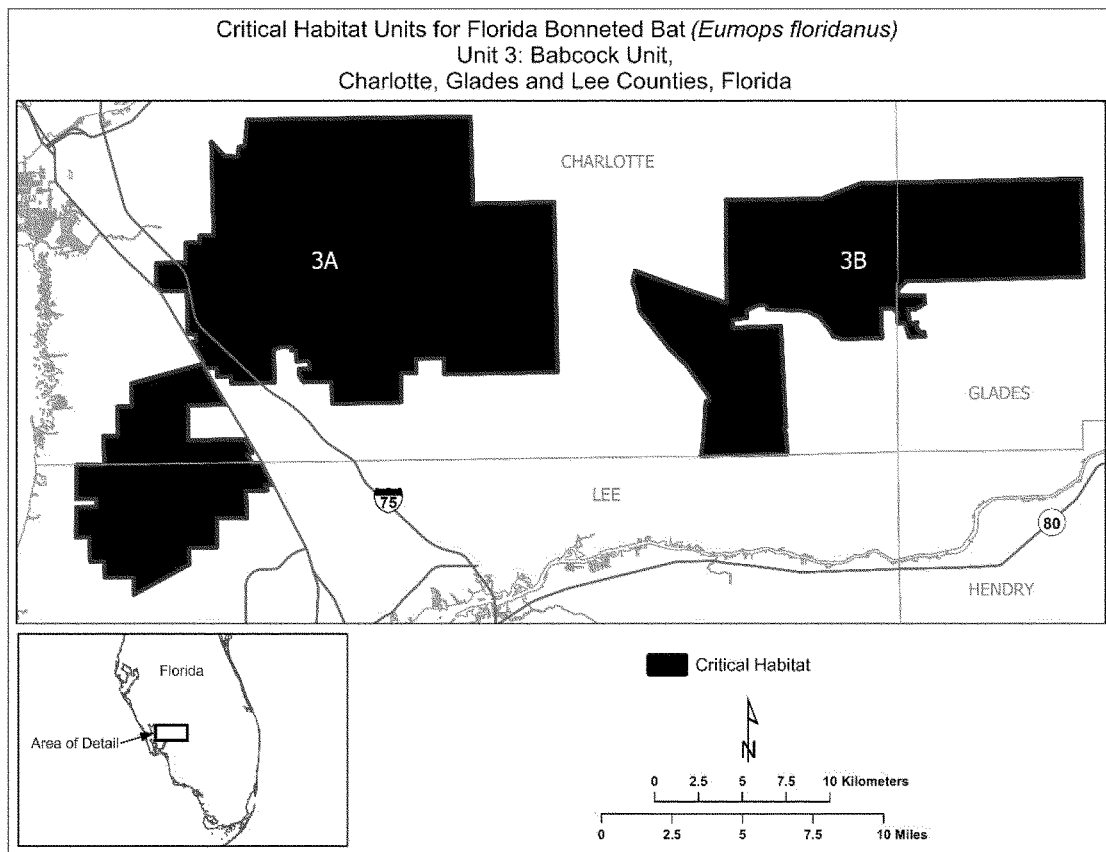


(8) Unit 3: Babcock Unit; Charlotte, Lee, and Glades Counties, Florida.

(i) Unit 3 encompasses 133,560 ac (54,050 ha) of lands in Charlotte, Lee, and Glades Counties, Florida. This unit

consists of two subunits, with the majority of Unit 3 located in Charlotte County, east of I-75; other portions are in northwestern Lee and western Glades Counties.

(ii) Map of Unit 3 follows:
 Figure 4 to Florida Bonneted Bat (*Eumops floridanus*) paragraph (8)(ii)

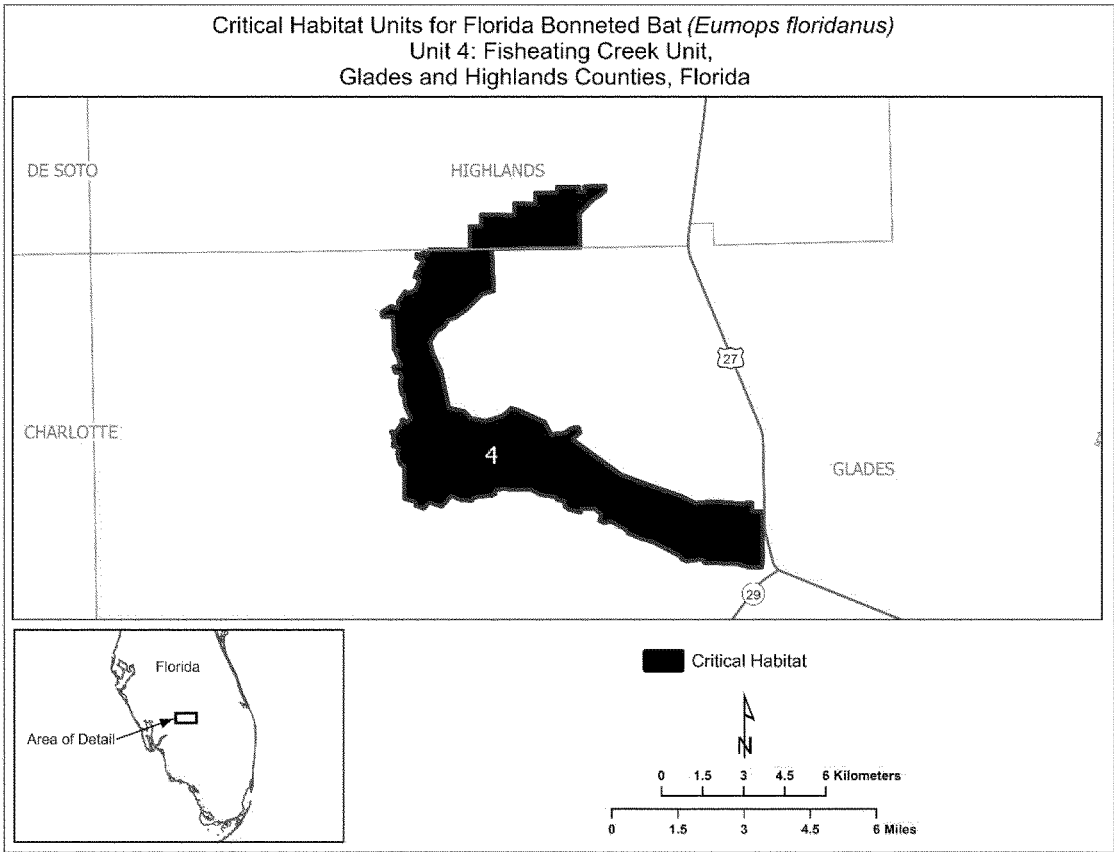


(9) Unit 4: Fisheating Creek Unit; Glades and Highlands Counties, Florida.
(i) Unit 4 encompasses 12,995 ac (5,259 ha) of lands in Glades and Highlands Counties, Florida. The majority of Unit

4 is located in Glades County, west of U.S.-27; the remainder of the unit extends north into southern Highlands County.

(ii) Map of Unit 4 follows:

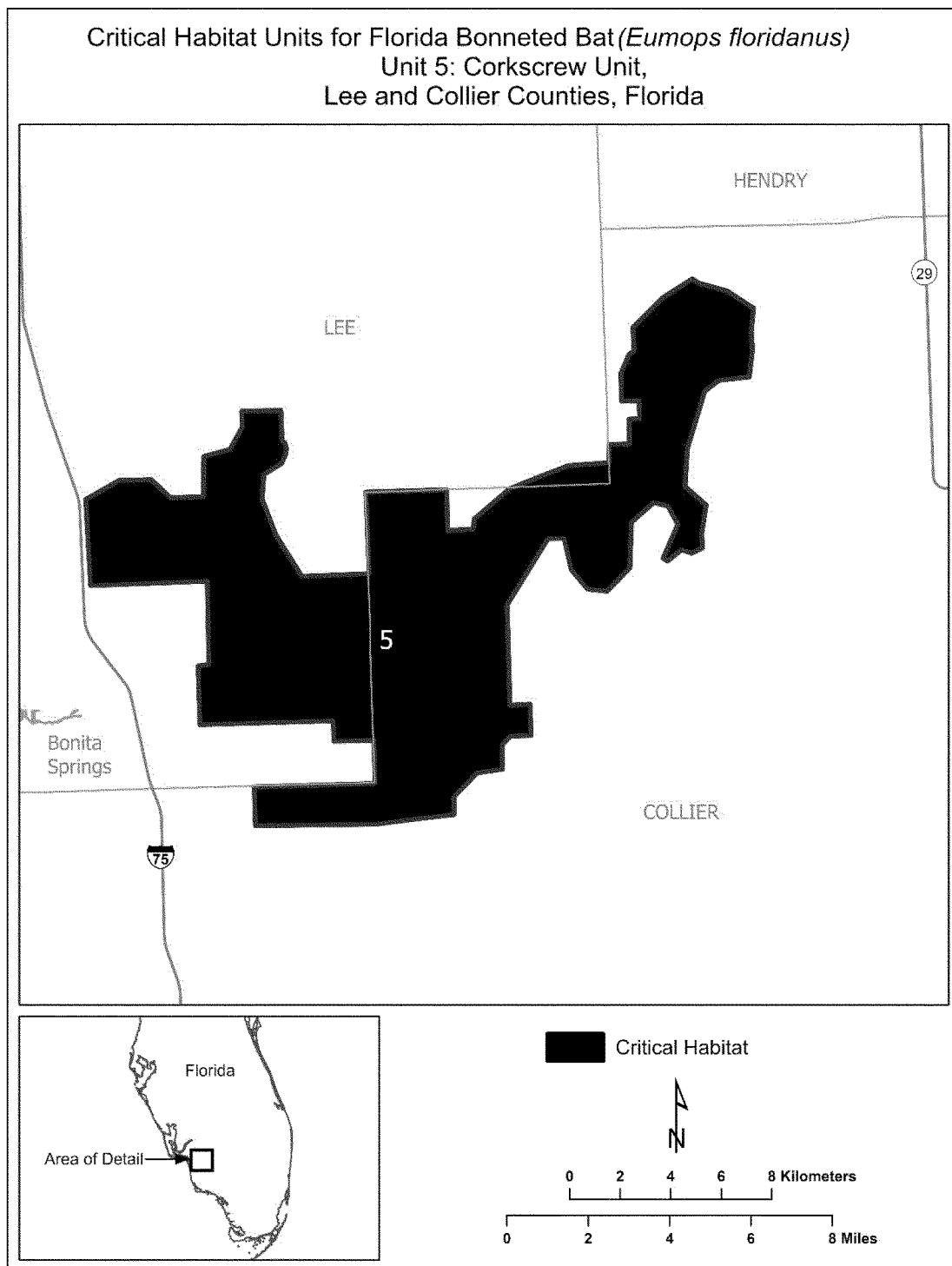
Figure 5 to Florida Bonneted Bat (*Eumops floridanus*) paragraph (9)(ii)



(10) Unit 5: Corkscrew Unit; Lee and Collier Counties, Florida.
(i) Unit 5 encompasses 48,865 ac (19,775 ha) of lands in Lee and Collier

Counties, Florida. This unit straddles the Lee/Collier county line, east of I-75.
(ii) Map of Unit 5 follows:

Figure 6 to Florida Bonneted Bat (*Eumops floridanus*) paragraph (10)(ii)



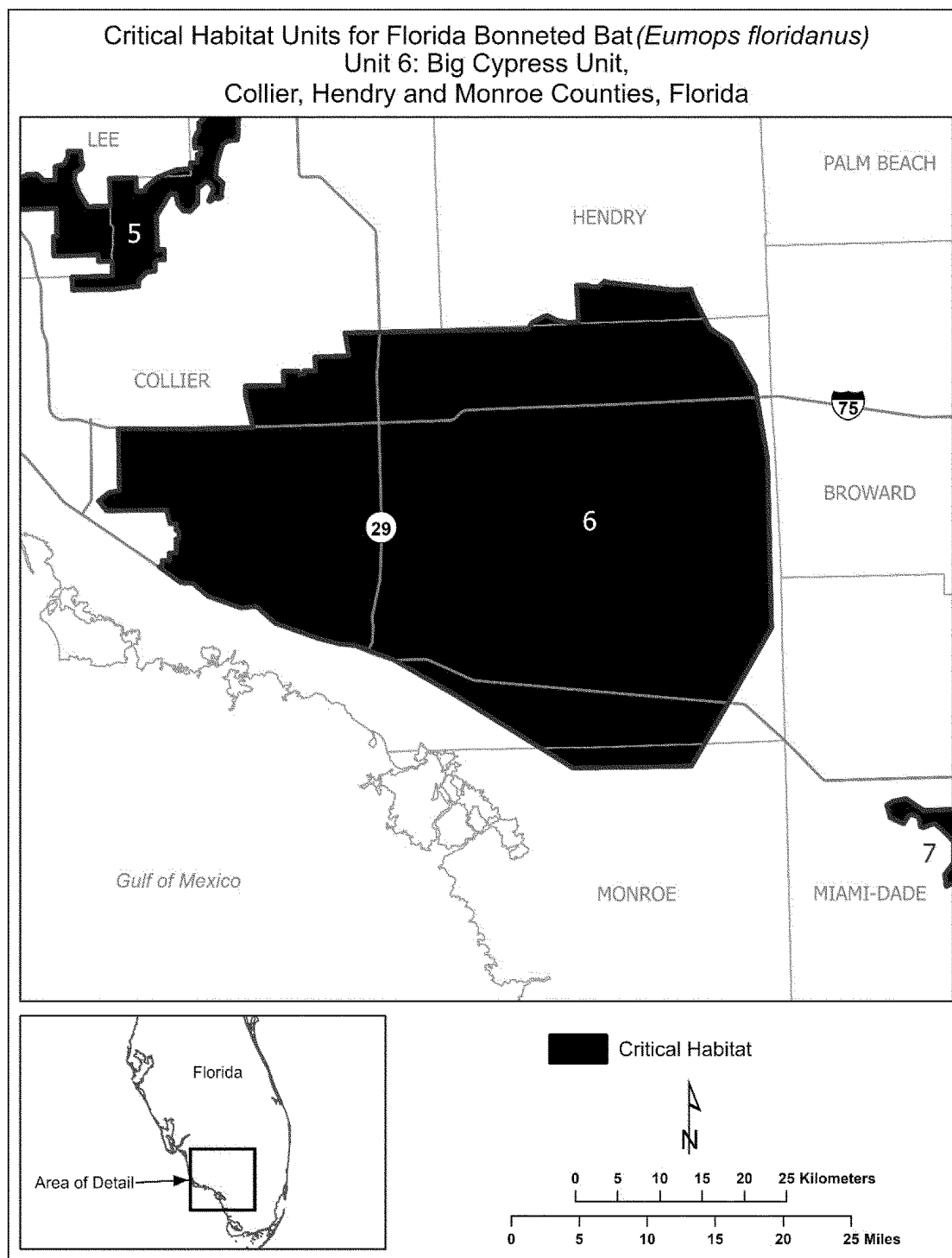
(11) Unit 6: Big Cypress Unit; Collier, Hendry, and Monroe Counties, Florida.

(i) Unit 6 encompasses 728,544 ac (294,831 ha) of lands in Collier, Hendry, and Monroe Counties, Florida. The

majority of Unit 6 is located in Collier County, south of I-75; the remainder of the unit occurs in southern Hendry County and mainland portions of Monroe County.

(ii) Map of Unit 6 follows:

Figure 7 to Florida Bonneted Bat (*Eumops floridanus*) paragraph (11)(ii)



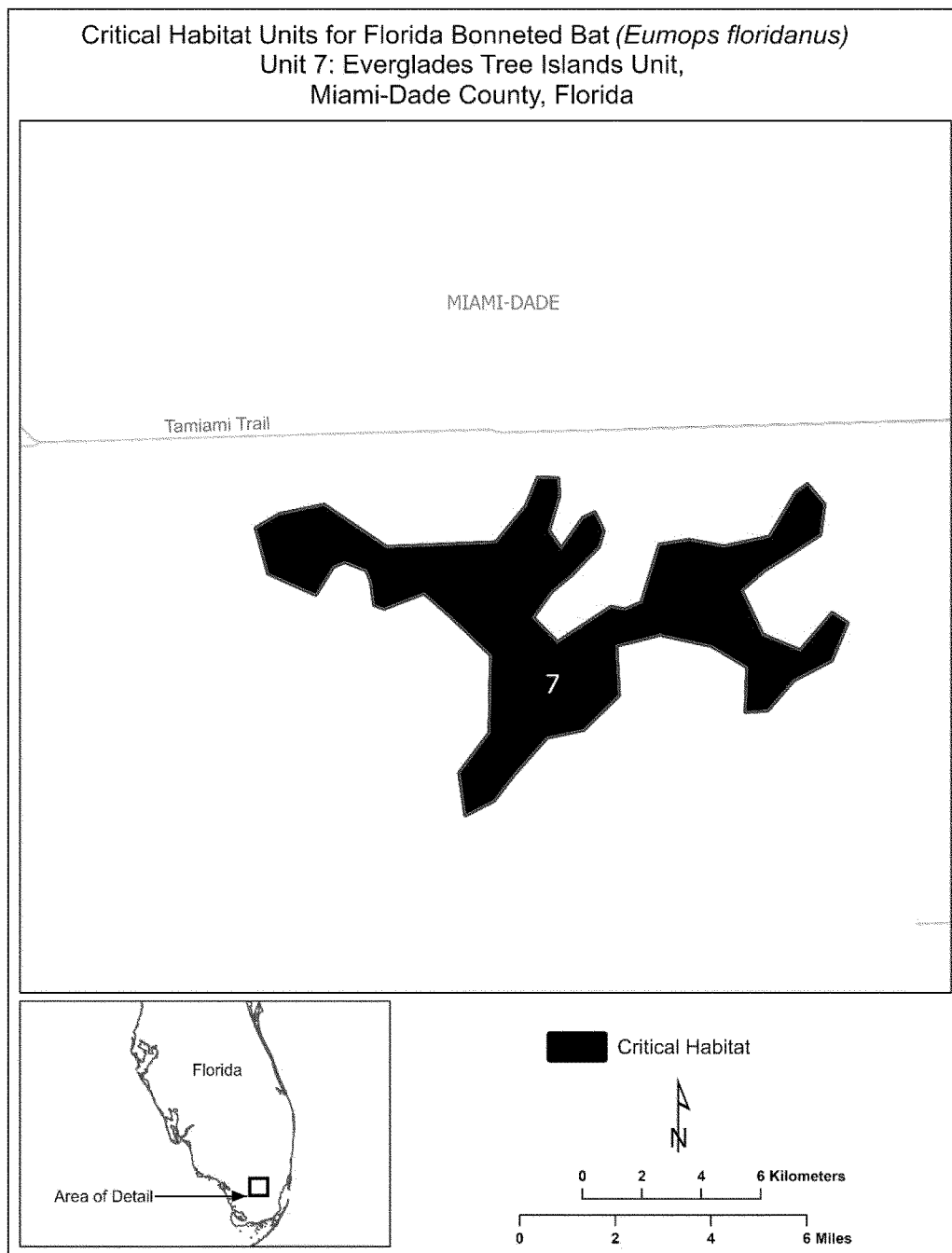
(12) Unit 7: Everglades Tree Islands Unit; Miami-Dade County, Florida.

(i) Unit 7 encompasses 16,604 ac (6,719 ha) of lands in Miami-Dade

County, Florida, south of Tamiami Trail and west of Krome Avenue.

(ii) Map of Unit 7 follows:

Figure 8 to Florida Bonneted Bat (*Eumops floridanus*) paragraph (12)(ii)



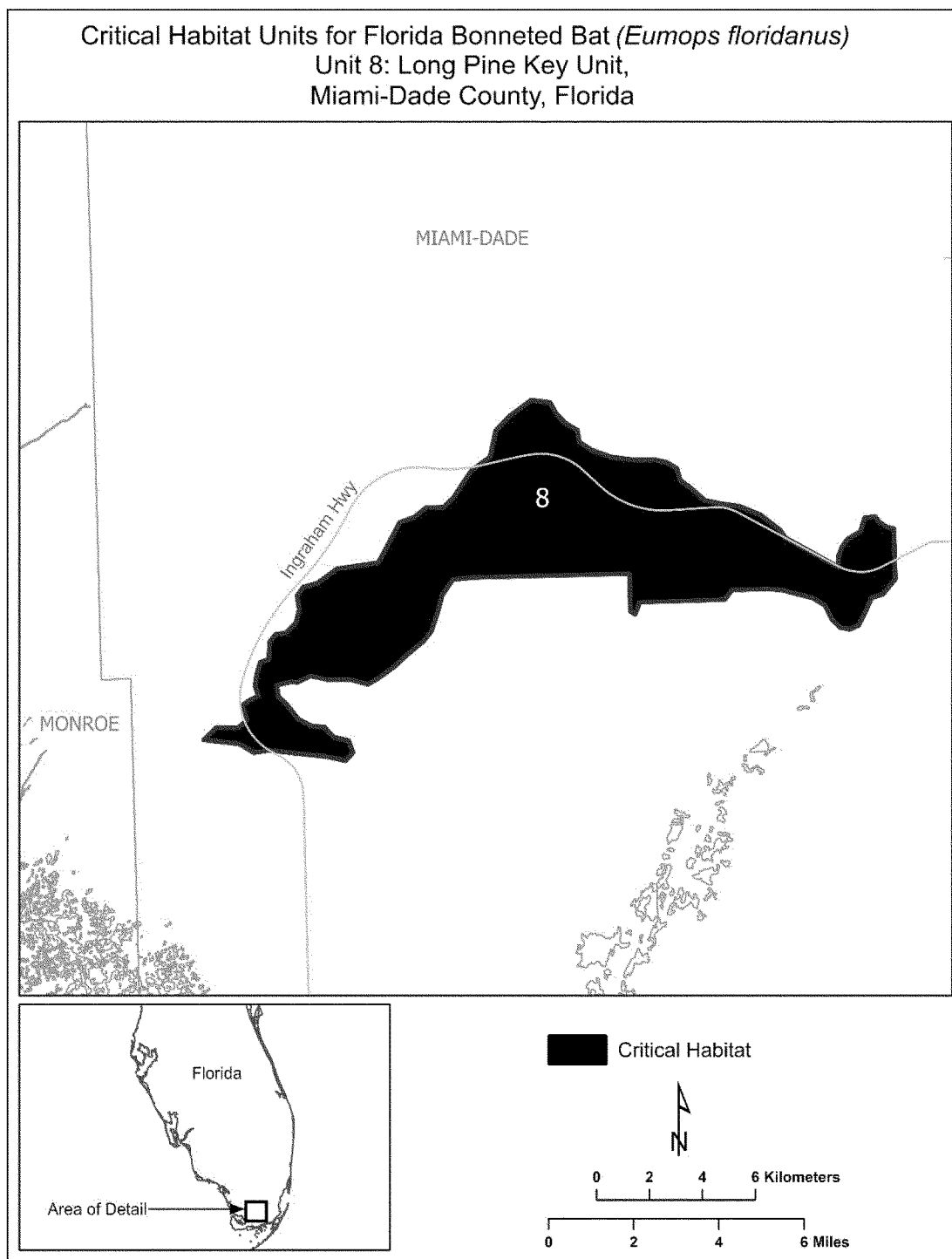
(13) Unit 8: Long Pine Key Unit;
Miami-Dade County, Florida.

(i) Unit 8 encompasses 25,337 ac
(10,254 ha) of lands in Miami-Dade

County, Florida, along Main Park Road
(SR-9336) between Mahogany
Hammock and SW 237th Avenue.

(ii) Map of Unit 8 follows:

Figure 9 to Florida Bonneted Bat
(*Eumops floridanus*) paragraph (13)(ii)



(14) Unit 9: Miami Rocklands Unit; Miami-Dade County, Florida.

(i) Unit 9 encompasses 4,324 ac (1,750 ha) of lands in Miami-Dade County, Florida. This unit consists of 36

subunits located between Tamiami Trail to the north and SR-9336 to the south, and is surrounded by a dense urban matrix typical of the Miami metropolitan area.

(ii) Maps of Unit 9 follow:

Figure 10 to Florida Bonneted Bat (*Eumops floridanus*) paragraph (14)(ii)

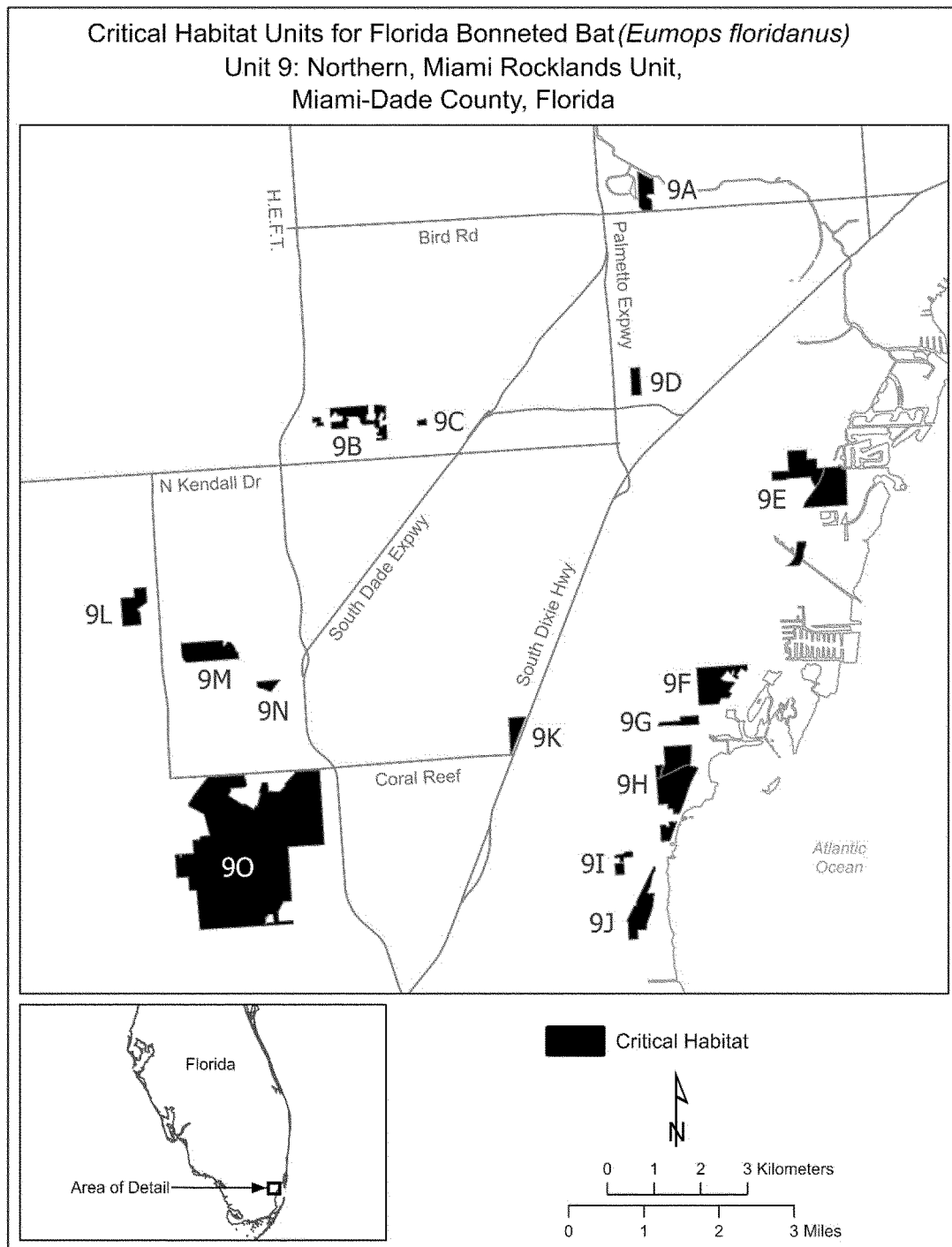


Figure 11 to Florida Bonneted Bat
(*Eumops floridanus*) paragraph (14)(ii)

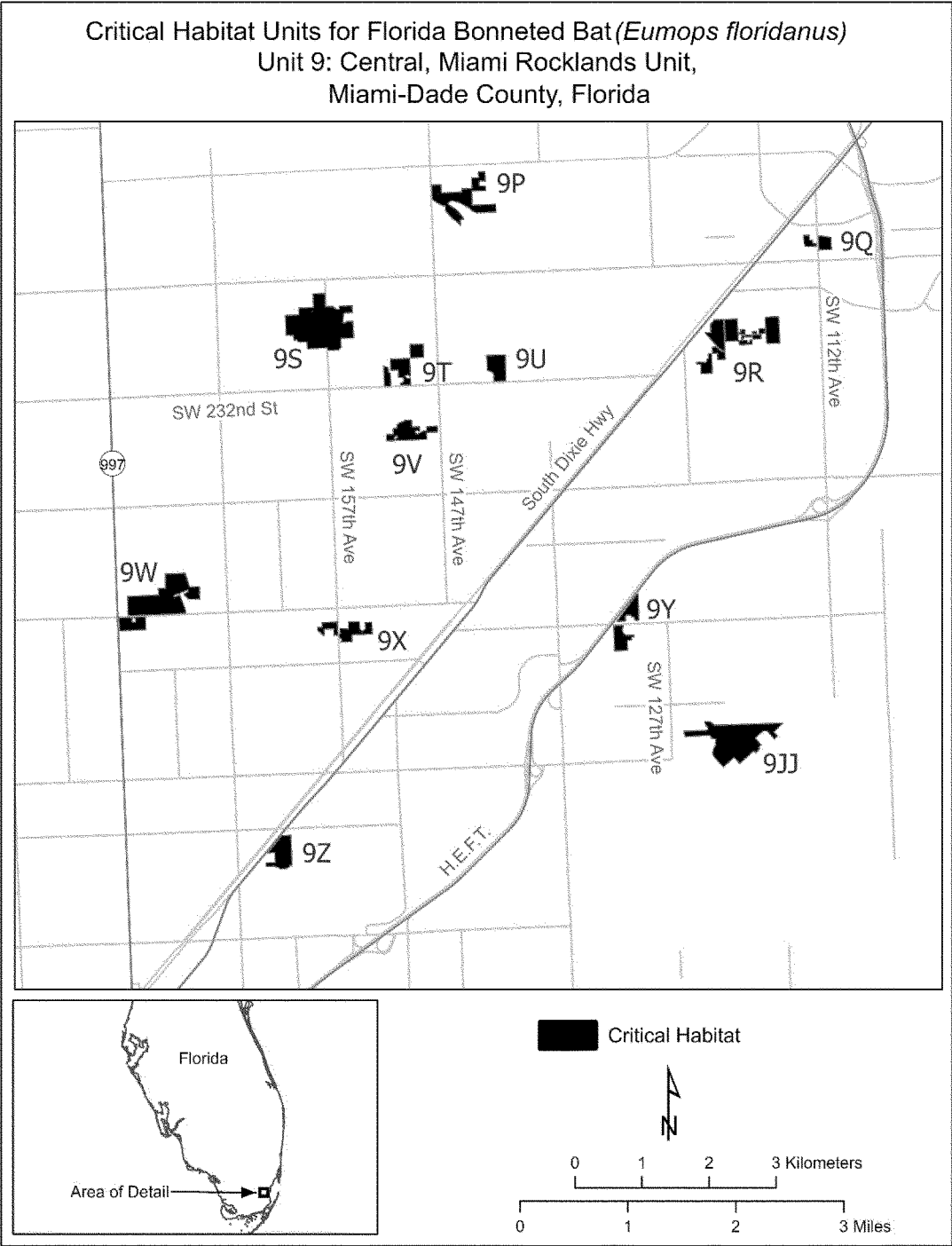
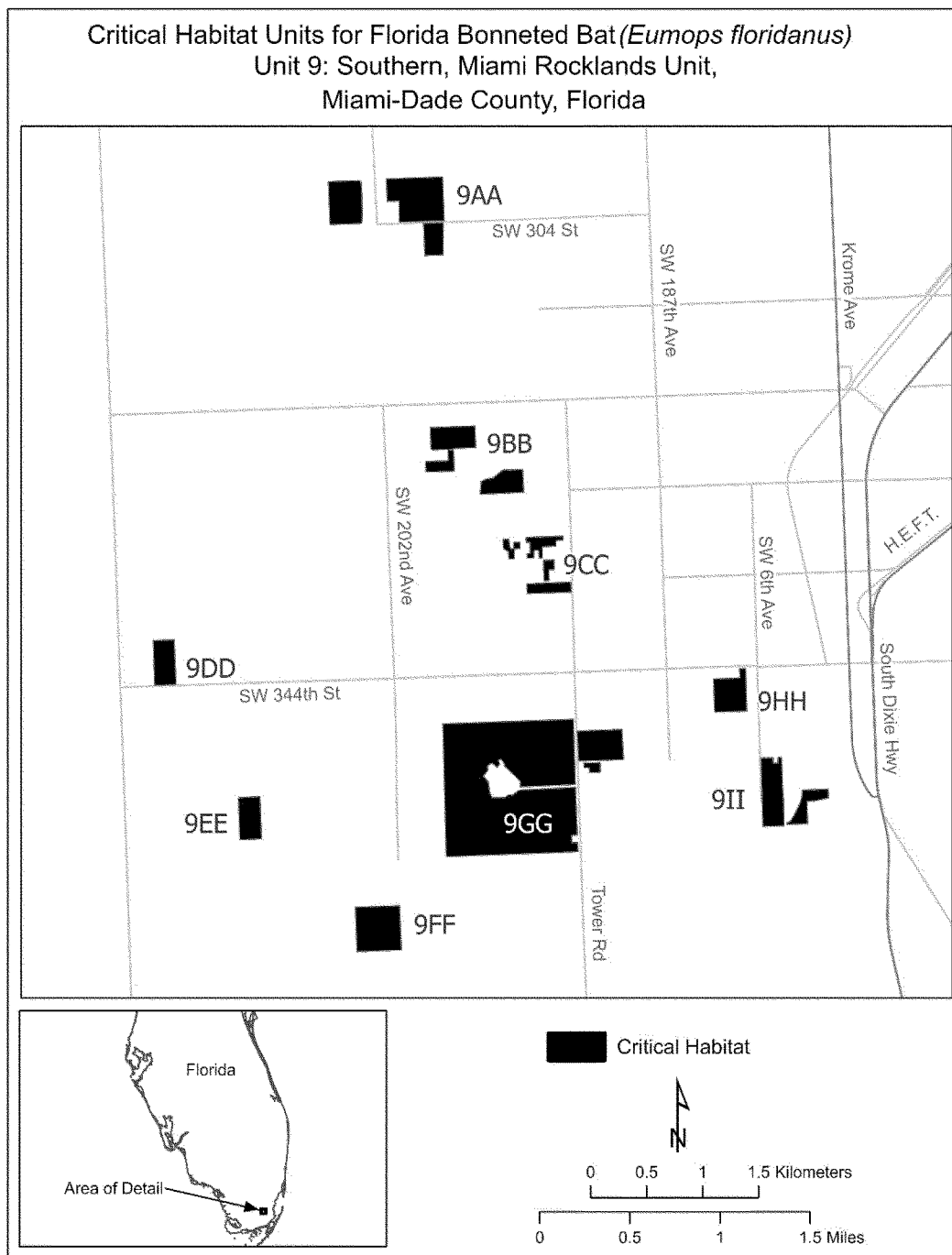


Figure 12 to Florida Bonneted Bat
(*Eumops floridanus*) paragraph (14)(ii)



* * * * *

Stephen Guertin,

*Acting Director, U.S. Fish and Wildlife
Service.*

[FR Doc. 2022-25218 Filed 11-21-22; 8:45 am]

BILLING CODE 4333-15-C

Reader Aids

Federal Register

Vol. 87, No. 224

Tuesday, November 22, 2022

CUSTOMER SERVICE AND INFORMATION

Federal Register/Code of Federal Regulations

General Information, indexes and other finding aids **202-741-6000****Laws** **741-6000**

Presidential Documents

Executive orders and proclamations **741-6000****The United States Government Manual** **741-6000**

Other Services

Electronic and on-line services (voice) **741-6020**Privacy Act Compilation **741-6050**

ELECTRONIC RESEARCH

World Wide Web

Full text of the daily Federal Register, CFR and other publications is located at: www.govinfo.gov.Federal Register information and research tools, including Public Inspection List and electronic text are located at: www.federalregister.gov.

E-mail

FEDREGTOC (Daily Federal Register Table of Contents Electronic Mailing List) is an open e-mail service that provides subscribers with a digital form of the Federal Register Table of Contents. The digital form of the Federal Register Table of Contents includes HTML and PDF links to the full text of each document.To join or leave, go to <https://public.govdelivery.com/accounts/USGPOOFR/subscriber/new>, enter your email address, then follow the instructions to join, leave, or manage your subscription.**PENS** (Public Law Electronic Notification Service) is an e-mail service that notifies subscribers of recently enacted laws.To subscribe, go to <http://listserv.gsa.gov/archives/publaws-l.html> and select *Join or leave the list (or change settings)*; then follow the instructions.**FEDREGTOC** and **PENS** are mailing lists only. We cannot respond to specific inquiries.**Reference questions.** Send questions and comments about the Federal Register system to: fedreg.info@nara.gov

The Federal Register staff cannot interpret specific documents or regulations.

FEDERAL REGISTER PAGES AND DATE, NOVEMBER

65649-66074.....	1
66075-66226.....	2
66227-66534.....	3
66535-66934.....	4
66935-67350.....	7
67351-67540.....	8
67541-67762.....	9
67763-68018.....	10
68019-68334.....	14
68335-68590.....	15
68591-68884.....	16
68885-69154.....	17
69155-70688.....	18
70701-71202.....	21
71203-71502.....	22

CFR PARTS AFFECTED DURING NOVEMBER

At the end of each month the Office of the Federal Register publishes separately a List of CFR Sections Affected (LSA), which lists parts and sections affected by documents published since the revision date of each title.

3 CFR

Proclamations:

10482.....	65649
10483.....	66515
10484.....	66517
10485.....	66519
10486.....	66521
10487.....	66525
10488.....	66527
10489.....	66529
10490.....	66531
10491.....	66533
10492.....	67763
10493.....	68019
10494.....	68591
10495.....	68593
10496.....	68885
10497.....	70701

Administrative Orders:

Memorandums:

October 28, 2022.....	67761
Memorandum of November 10, 2022.....	71201
Notices:	
Notice of November 1, 2022.....	66225
Notice of November 8, 2022.....	68013
Notice of November 8, 2022.....	68015
Notice of November 8, 2022.....	68017
Notice of November 10, 2022.....	68589

5 CFR

315.....	67765
432.....	67765
752.....	67765
875.....	68595
Proposed Rules:	
841.....	68642
842.....	68642

6 CFR

5.....	68599
--------	-------

7 CFR

205.....	68021
272.....	68335
273.....	68335
1230.....	66535
3550.....	66075
3555.....	66075
Proposed Rules:	
246.....	71090
906.....	69208
993.....	66958
1206.....	65683
1222.....	66960

10 CFR

Ch. I.....	66228, 68335
20.....	68028
26.....	71422
35.....	68028
50.....	66227, 68028
51.....	68028
52.....	66227, 68028
72.....	66539, 68028
73.....	68028
110.....	68028
150.....	68028
429.....	65651, 65856, 66935
430.....	66935
431.....	65651, 65856

Proposed Rules:

37.....	67397
50.....	67571
72.....	66613
430.....	65687, 68931, 69082
1021.....	68385

12 CFR

Ch. X.....	66935, 66940
201.....	68887
204.....	68888
1006.....	65668
1091.....	70703

13 CFR

121.....	69118
124.....	69118
127.....	69118

Proposed Rules:

107.....	68109
120.....	66963
121.....	68109

14 CFR

11.....	70707
13.....	66544
25.....	68336, 71203
39.....	65670, 66077, 66080, 66084, 66942, 67351, 67354, 67359, 67361, 67541, 67543, 67545, 67783, 68608, 68610, 68614, 68616, 68618, 68621, 68624, 68889, 68891, 69155, 69158, 69161, 70708, 70711
47.....	71210
61.....	71218
68.....	71218
71.....	65673, 65674, 65675, 65677, 65679, 65680, 66229, 66544, 66946, 66947, 67547, 68627, 69164, 71238
73.....	66978
91.....	70707
97.....	68628, 68630
111.....	70707
1212.....	71240
Proposed Rules:	
21.....	67399

25.....68942	206.....70733	6.....68908	45 CFR
39.....65694, 66615, 66619, 66623, 66625, 66971, 67572, 67575, 67579, 67581, 67834, 67837, 67840, 67842, 67845, 67849, 68109, 68113, 68644, 69210, 69214, 69218, 69220, 69222, 69225, 69228, 69231, 71264	25 CFR	111.....69171	Proposed Rules:
259.....68944	537.....68046	Proposed Rules:	162.....67634
260.....68944	571.....67363	36.....65700	46 CFR
71.....66627, 66629, 66630, 66632, 66633, 66634, 66636, 66974, 66975, 67584, 68116, 71266	Proposed Rules:	111.....67615	10.....66575
399.....68944	571.....67430	3030.....69236	11.....66575
15 CFR	26 CFR	40 CFR	15.....66575
90.....71240	1.....68048, 68898	52.....67789, 68057, 68364, 68632, 68634, 69177, 71258	121.....68270
Proposed Rules:	Proposed Rules:	55.....68364	160.....68270
90.....71269	1.....71271	60.....67558	169.....68270
16 CFR	300.....67611	61.....67558	184.....68270
1239.....68032	27 CFR	63.....67558, 67791	199.....68270
1460.....71242	Proposed Rules:	131.....69183	Proposed Rules:
Proposed Rules:	6.....67612	141.....68060	541.....68416
453.....66096	8.....67612	152.....67364	47 CFR
464.....67413	10.....67612	180.....66554, 67371, 67375, 68909, 69201	11.....67808
465.....67424	11.....67612	Proposed Rules:	64.....67826, 69206
1270.....67586	28 CFR	2.....68946	73.....67827
17 CFR	2.....66549	51.....68119	Proposed Rules:
240.....66412	50.....66239	52.....65714, 65719, 66086, 66091, 66985, 67617, 68119, 68410, 68413, 68414, 70758, 71286	54.....67660
Proposed Rules:	29 CFR	81.....65719	64.....68416
275.....68816	1400.....68357	84.....66372	73.....68432, 68960, 70765
279.....68816	1404.....69165	180.....68959	48 CFR
19 CFR	Proposed Rules:	700.....68647	801.....70745
102.....68338	103.....66890	42 CFR	802.....70745
Proposed Rules:	1400.....67852	400.....66454	808.....70745
351.....69234	2550.....70753	405.....69404	816.....70745
21 CFR	2560.....71164	406.....66454	819.....71262
1.....70910	2570.....71164	407.....66454	835.....70745
73.....67785	4213.....67853	408.....66454	852.....70745, 71262
866.....66545	33 CFR	410.....66454, 69404	Proposed Rules:
1271.....65861	100.....66244, 70744, 71251	411.....69404	1.....68312
1301.....66954, 68036	117.....68049	412.....66558	4.....68312
1308.....67548, 68895, 70715, 70717, 71247	165.....66086, 66550, 66552, 66955, 68051, 68053, 68358, 69166, 71252	413.....66558, 67136	9.....68312
1309.....68036	Proposed Rules:	414.....69404	23.....68312
1310.....67550	203.....68386	415.....69404	52.....68312
1316.....68036	165.....67430, 67433	423.....66454, 69404	49 CFR
Proposed Rules:	34 CFR	424.....69404	223.....68913
50.....68118	600.....65904, 68900	425.....69404	365.....68367
56.....68118	668.....65904, 68900	431.....66454	371.....68635
80.....66116	674.....65904	435.....66454	387.....68367
173.....70752	682.....65904	455.....69404	390.....68367
812.....68118	685.....65904	482.....66558	Proposed Rules:
22 CFR	690.....68900	484.....66790	218.....66638
126.....71250	36 CFR	485.....66558	350.....68433
212.....70721	1151.....69168	493.....68912	50 CFR
23 CFR	37 CFR	495.....66558	17.....66093, 66591, 67380, 68381
630.....67553	Proposed Rules:	512.....67136	21.....66094
635.....67553	1.....69235	Proposed Rules:	622.....66608, 68382
24 CFR	210.....71286	422.....65723	635.....68104
201.....70733	385.....66976	423.....65723	648.....66245, 67829, 67830, 68925, 70751
203.....70733	38 CFR	438.....65723	660.....66609, 71262
	3.....68360, 68904	498.....65723	679.....66611, 67832, 68383, 68384, 68640
	17.....71254	43 CFR	Proposed Rules:
	39 CFR	8360.....69204	Ch. 1.....66255
	3.....68908	Proposed Rules:	17.....66987, 68975, 71466
		2800.....67306	20.....66247
		2860.....67306	223.....67853
		2880.....67306	300.....70766
		2920.....67306	648.....66120, 68434
		44 CFR	679.....65724, 66125, 67665
		296.....68085	680.....65724

LIST OF PUBLIC LAWS

Note: No public bills which have become law were received by the Office of the Federal Register for inclusion

in today's **List of Public Laws**.

Last List October 20, 2022

Public Laws Electronic Notification Service (PENS)

PENS is a free email notification service of newly

enacted public laws. To subscribe, go to https://portalguard.gsa.gov/__layouts/PG/register.aspx.

Note: This service is strictly for email notification of new laws. The text of laws is not available through this service. **PENS** cannot respond to specific inquiries sent to this address.